A PRESCRIPTION FOR SAFETY: THE NEED FOR H.R. 3880, THE INTERNET PHARMACY CONSUMER PROTECTION ACT

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

MARCH 18, 2004

Serial No. 108–169

Printed for the use of the Committee on Government Reform

Available via the World Wide Web: http://www.gpo.gov/congress/house
http://www.house.gov/reform

U.S. GOVERNMENT PRINTING OFFICE

94–903 PDF WASHINGTON : 2004

For sale by the Superintendent of Documents, U.S. Government Printing Office
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A PRESCRIPTION FOR SAFETY: THE NEED FOR H.R. 3880, THE INTERNET PHARMACY CONSUMER PROTECTION ACT

THURSDAY, MARCH 18, 2004

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 10:17 a.m., in room 2154, Rayburn House Office Building, Hon. Tom Davis of Virginia (chairman of the committee) presiding.

Present: Representatives Tom Davis of Virginia, Shays, Souder, Ose, Schrock, Duncan, Murphy, Turner, Carter, Harris, Waxman, Towns, Clay, Watson, Van Hollen, and Norton.

Staff present: Melissa Wojciak, staff director; David Marin, deputy staff director and director of communications; Anne Marie Turner, counsel; Drew Crockett, deputy director of communications; Teresa Austin, chief clerk; Brien Beattie, deputy clerk; Susie Schulte, professional staff member; Corinne Zaccagnini, chief information officer; Phil Barnett, minority staff director; Kristin Amerling, minority deputy chief counsel; Josh Sharfstein, minority professional staff member; Earley Green, minority chief clerk; and Jean Gosa, minority assistant clerk.

Chairman TOM DAVIS. Good morning. A quorum being present, the Committee on Government Reform will come to order.

I'd like to welcome everybody to today's legislative hearing on H.R. 3880, the Internet Pharmacy Consumer Protection Act. This hearing will focus on how to curb, through legislation, the growing sale of prescription drugs over the Internet without a valid prescription.

Prescription drugs are well regulated in this country by a system that includes pre-market approval by the FDA, State licensure of health care practitioners who are allowed to prescribe and State oversight of pharmacists and pharmacies. However, as noted in previous committee hearings and recent media reports, the Internet creates an easy environment for illegitimate pharmacy Web sites to bypass traditional regulations and established safeguards for the sale of prescription drugs.

I think all of us here today have opened our in-boxes to find dozens of e-mails advertising medications at low cost with no prescriptions required. The risks of this kind of self-medicating can include adverse reactions from inappropriately prescribed medications, dangerous drug interactions, use of counterfeit or tainted products and addiction to habit forming substances.

Mr. Waxman and I recently introduced H.R. 3880, because too many people are finding ways to obtain medications online without valid prescriptions. And regulating those Internet pharmacies can be a challenge for Federal and State enforcement capabilities. H.R. 3880 amends the Food, Drug and Cosmetic Act to address this problem in three steps.

First, the bill establishes disclosure standards for Internet pharmacies. These Web sites are required to display certain identifying information, including the name of the business, pharmacist and physician associated with the Web site. Second, the bill prohibits Internet sites from selling or dispensing a prescription drug solely on the basis of an online questionnaire. Online medical evaluations don't meet reasonable standards of care and create risks for the consumers. And third, the bill provides additional authority for States to take actions against illegal Internet pharmacies. The bill allows States attorneys general to file an injunction in Federal court to shut down a rogue site across the country.

The need for legislation is critical. And I say this as someone who is normally more than a little hesitant to regulate the Internet or hinder commerce. The illegal diversion and abuse of prescription drugs is becoming an increasingly serious problem in this country. Last March, several of the witnesses who are joining us again today highlighted this problem in their testimony and asked for help from Congress. Mr. Waxman and I gave it deliberate consideration and responded with legislation to help protect consumers and aid Federal and State enforcement and regulatory capabilities.

As we hold this discussion on the legislation today, it's important to clarify that H.R. 3880 is intended to tackle domestic Internet pharmacies that sell drugs without a valid prescription. The bill is not intended to address international pharmacies that sell drugs at a low cost to consumers who have a valid prescription from their U.S. doctors. Although the debate over reimportation is an important one, it's not the focus of this hearing.

I want to thank our ranking member, Henry Waxman, for his efforts and leadership on this legislation and his commitment to public health. I would also like to thank our witnesses for their participation today, and I look forward to their testimony. I'm happy to extend a very specific welcome to my good friend, Jerry Kilgore, who is the Attorney General of my home State of Virginia, who's here today representing the National Association of Attorneys General. Jerry, thanks for being with us.

[The prepared statement of Chairman Tom Davis follows:]

Statement of Chairman Tom Davis
Committee on Government Reform
Hearing on "A Prescription for Safety: the Need for H.R. 3880, the Internet Pharmacy Consumer Protection Act"
March 18, 2004

Good morning, a quorum being present, the Committee on Government Reform will come to order. I would like to welcome everyone to today's legislative hearing on H.R. 3880, the Internet Pharmacy Consumer Protection Act. This hearing will focus on how to curb, through legislation, the growing sale of prescription drugs over the Internet without a valid prescription.

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Mr. Waxman and I recently introduced H.R. 3880 because too many people are finding ways to obtain medications online without valid prescriptions, and regulating these Internet pharmacies can be a challenge for federal and state enforcement capabilities. H.R. 3880 amends the Food, Drug, and Cosmetic Act to address this problem in three steps.

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I would like to thank the Committee's Ranking Member, Henry Waxman, for his efforts on this legislation and his commitment to public health. I would also like to thank our witnesses for their participation today, and I look forward to their testimony. I'm happy to extend a specific welcome to my friend Jerry Kilgore, the Attorney General of my home state of Virginia, who's here today representing the National Association of Attorneys General.

I

108TH CONGRESS
2D SESSION

H. R. 3880

To amend the Federal Food, Drug, and Cosmetic Act with respect to the sale of prescription drugs through the Internet.

IN THE HOUSE OF REPRESENTATIVES

MARCH 3, 2004

Mr. TOM DAVIS of Virginia (for himself and Mr. WAXMAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the sale of prescription drugs through the Internet.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Internet Pharmacy Consumer Protection Act".

SEC. 2. INTERNET SALES OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter 5 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503A the following section:

"SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.

"(a) REQUIREMENTS REGARDING INFORMATION ON INTERNET SITE.—

"(1) IN GENERAL.—A person may not dispense a prescription drug pursuant to a sale of the drug by such person if—

"(A) the purchaser of the drug submitted the purchase order for the drug, or conducted any other part of the sales transaction for the drug, through an Internet site; and

"(B) such site, or any other Internet site used by such person for purposes of sales of a prescription drug, fails to meet each of the requirements specified in paragraph (2) (other than a site or pages on a site that are not intended to be accessed by purchasers or prospective purchasers or that provide an Internet information location tool within the meaning of section 231(e)(5) of the Communications Act of 1934 (47 U.S.C. 231(e)(5)).

"(2) REQUIREMENTS.—With respect to an Internet site, the requirements referred to in subparagraph (B) of paragraph (1) for a person to whom such paragraph applies are as follows:

"(A) Each page of the site shall include either the following information or a link to a page that provides the following information:

"(i) The name of such person; the address of the principal place of business of the person with respect to sales of prescription drugs through the Internet; and the telephone number for such place of business.

"(ii) Each State in which the person is authorized by law to dispense prescription drugs.

"(iii) The name of each individual who serves as a pharmacist for purposes of the site, and each State in which the individual is authorized by law to dispense prescription drugs.

"(iv) If the person provides for medical consultations through the site for purposes of providing prescriptions, the name of each individual who provides such consultations; each State in which the individual is licensed or otherwise authorized by law to provide such consultations or practice medicine; and the type or types of

health professions for which the individual holds such licenses or other authorizations.

"(B) A link to which paragraph (1) applies shall be displayed in a clear and prominent place and manner, and shall include in the caption for the link the words 'licensing and contact information'.

"(b) INTERNET SALES WITHOUT APPROPRIATE MEDICAL RELATIONSHIPS.—

"(1) IN GENERAL.—A person may not dispense a prescription drug, or sell such a drug, if—

"(A) for purposes of such dispensing or sale, the purchaser communicated with the person through the Internet;

"(B) the patient for whom the drug was dispensed or purchased did not, when such communications began, have a prescription for the drug that is valid in the United States;

"(C) pursuant to such communications, the person provided for the involvement of a practitioner, or an individual represented by the person as a practitioner, and the practitioner or such individual issued a prescription for the drug that was purchased;

"(D) the person knew, or had reason to know, that the practitioner or the individual referred to in subparagraph (C) did not, when issuing the prescription, have a qualifying medical relationship with the patient; and

"(E) the person received payment for the dispensing or sale of the drug.

For purposes of subparagraph (E), payment is received if money or other other valuable consideration is received.

"(2) QUALIFYING MEDICAL RELATIONSHIP.—

"(A) IN GENERAL.—With respect to issuing a prescription for a drug for a patient, a practitioner has a qualifying medical relationship with the patient for purposes of this section if at least one in-person medical evaluation of the patient has been conducted by the practitioner.

"(B) IN-PERSON MEDICAL EVALUATION.—A medical evaluation by a practitioner is an in-person medical evaluation for purposes of this section if the practitioner is in the physical presence of the patient as part of conducting the evaluation, without regard to whether por-

tions of the evaluation are conducted by other health professionals.

"(3) RULES OF CONSTRUCTION.—

"(A) INDIVIDUALS REPRESENTED AS PRACTITIONERS.—A person who is not a practitioner (as defined in subsection (d)(2)) lacks legal capacity under this section to have a qualifying medical relationship with any patient.

"(B) APPLICABILITY OF REQUIREMENTS.—Paragraph (1) may not be construed as having any applicability beyond this section, and does not affect any State law, or interpretation of State law, concerning the practice of medicine.

"(C) STANDARD PRACTICE OF PHARMACY.—Paragraph (1) may not be construed as prohibiting any conduct that is a standard practice in the practice of pharmacy.

"(c) ACTIONS BY STATES.—

"(1) IN GENERAL.—Whenever an attorney general of any State has reason to believe that the interests of the residents of that State have been or are being threatened or adversely affected because any person has engaged or is engaging in a pattern or practice that violates section 301(l), the State

may bring a civil action on behalf of its residents in an appropriate district court of the United States to enjoin such practice, to enforce compliance with such section (including a nationwide injunction), to obtain damages, restitution, or other compensation on behalf of residents of such State, to obtain reasonable attorneys fees and costs if the State prevails in the civil action, or to obtain such further and other relief as the court may deem appropriate.

"(2) NOTICE.—The State shall serve prior written notice of any civil action under paragraph (1) or (5)(B) upon the Secretary and provide the Secretary with a copy of its complaint, except that if it is not feasible for the State to provide such prior notice, the State shall serve such notice immediately upon instituting such action. Upon receiving a notice respecting a civil action, the Secretary shall have the right—

"(A) to intervene in such action;

"(B) upon so intervening, to be heard on all matters arising therein; and

"(C) to file petitions for appeal.

"(3) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in this chapter shall prevent an attorney general of a

State from exercising the powers conferred on the attorney general by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses or the production of documentary and other evidence.

"(4) VENUE; SERVICE OF PROCESS.—Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business or wherever venue is proper under section 1391 of title 28, United States Code. Process in such an action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

"(5) ACTIONS BY OTHER STATE OFFICIALS.—

"(A) Nothing contained in this section shall prohibit an authorized State official from proceeding in State court on the basis of an alleged violation of any civil or criminal statute of such State.

"(B) In addition to actions brought by an attorney general of a State under paragraph (1), such an action may be brought by officers of such State who are authorized by the State

to bring actions in such State on behalf of its residents.

"(d) DEFINITIONS.—

"(1) INTERNET-RELATED DEFINITIONS.—For purposes of this section:

"(A) The term 'Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected world-wide network of networks that employ the transmission control protocol/internet protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire or radio.

"(B) The term 'link', with respect to the Internet, means one or more letters, words, numbers, symbols, or graphic items that appear on a page of an Internet site for the purpose of serving, when activated, as a method for executing an electronic command—

"(i) to move from viewing one portion of a page on such site to another portion of the page;

"(ii) to move from viewing one page on such site to another page on such site; or

"(iii) to move from viewing a page on one Internet site to a page on another Internet site.

"(C) The term 'page', with respect to the Internet, means a document or other file accessed at an Internet site.

"(D)(i) The terms 'site' and 'address', with respect to the Internet, mean a specific location on the Internet that is determined by Internet Protocol numbers. Such term includes the domain name, if any.

"(ii) The term 'domain name' means a method of representing an Internet address without direct reference to the Internet Protocol numbers for the address, including methods that use designations such as '.com', '.edu', '.gov', '.net', or '.org'.

"(iii) The term 'Internet Protocol numbers' includes any successor protocol for determining a specific location on the Internet.

"(2) OTHER DEFINITIONS.—For purposes of this section:

"(A) The term 'practitioner' means a practitioner referred to in section 503(b)(1) with respect to issuing a written or oral prescription.

"(B) The term 'prescription drug' means a drug that is subject to section 503(b)(1).

"(C) The term 'qualifying medical relationship', with respect to a practitioner and a patient, has the meaning indicated for such term in subsection (b).

"(e) INTERACTIVE COMPUTER SERVICE; ADVERTISING.—No provider of an interactive computer service, as defined in section 230(f)(2) of the Communications Act of 1934 (47 U.S.C. 230(f)(2)), or of advertising services shall be liable under this section for dispensing or selling prescription drugs in violation of this section on account of another person's selling or dispensing such drugs, provided that the provider of the interactive computer service or of advertising services does not own or exercise corporate control over such person.".

(b) INCLUSION AS PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by inserting after paragraph (k) the following:

"(l) The dispensing or selling of a prescription drug in violation of section 503B.".

(c) INTERNET SALES OF PRESCRIPTION DRUGS; CONSIDERATION BY SECRETARY OF PRACTICES AND PROCEDURES FOR CERTIFICATION OF LEGITIMATE BUSINESSES.—In carrying out section 503B of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section), the Secretary of Health and Human Services shall take into consideration the practices and procedures of public or private entities that certify that businesses selling prescription drugs through Internet sites are legitimate businesses, including practices and procedures regarding disclosure formats and verification programs.

(d) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) take effect upon the expiration of the 60-day period beginning on the date of the enactment of this Act, without regard to whether a final rule to implement such amendments has been promulgated by the Secretary of Health and Human Services under section 701(a) of the Federal Food, Drug, and Cosmetic Act. The preceding sentence may not be construed as affecting the authority of such Secretary to promulgate such a final rule.

SEC. 3. REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF STATE AND FEDERAL LAWS ON DISPENSING OF DRUGS.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall, pursuant to the submission of an application meeting the criteria of the Secretary, make an award of a grant or contract to the National Clearinghouse on Internet Prescribing (operated by the Federation of State Medical Boards) for the purpose of—

(1) identifying Internet sites that appear to be in violation of State or Federal laws concerning the dispensing of drugs;

(2) reporting such sites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

(3) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken with respect to violations described in paragraph (1).

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out subsection (a), there is authorized to be appropriated $100,000 for each of the fiscal years 2004 through 2006.

○

Chairman TOM DAVIS. I will now yield to Mr. Waxman for an opening statement.

Mr. WAXMAN. I'd like to thank Chairman Davis for holding this hearing today on how to stop domestic Web sites from selling potentially dangerous medications without a valid prescription. These Web sites occupy a dark and dangerous corner of the U.S. health care system. But they are not hidden. A simple e-mail may entice consumers, even children, to order potentially dangerous drugs prescribed on the basis of a cursory questionnaire by an anonymous physician.

In fact, just last night, one of my staff members, in preparing for the hearing today, received an unsolicited e-mail message offering overnight delivery of Viagra. I have a poster over there that points out the Web site and that the e-mail was linked to. This Web site offers many potentially dangerous medications, including some controlled substances. The Web page promises "FDA approved drugs" and states "one of our U.S. licensed physicians will review your request and issue prescriptions for your medication."

I would note that the Web page does not state that a physician will determine whether this medication is right for you. It does require that the user enter all credit card and shipping information before any online consultation occurs.

[The information referred to follows:]

[redacted] Online Ordering of Prescription Drugs Fed.

HOME PAGE | ORDER STATUS | REORDER | CONTACT US | AFFILIATE PROGRAM

SEXUAL PERFORMANCE

Viagra	faq
Levitra NEW	faq
Cialis NEW	faq

WEIGHT LOSS

Phentermine	faq
Xenical	faq
Phendimetrazine	faq
Didrex	faq
Tenuate	faq
Adipex	faq
Ionamin	faq
Bontril	faq
Meridia	faq

MUSCLE RELAXERS

Carisoprodol	faq
Soma	faq
Fiorocet	faq
Cyclobenzaprine	faq
Flexeril	faq
Flextra	faq
Skelaxin	faq
Zanaflex	faq

SLEEP DEPRIVATION

Ambien	faq
Sonata	faq

HAIR LOSS PREVENTION

Propecia	faq

SKIN CARE

Renova	faq
Retin-A	faq
Nizoral	faq
Vaniqa	faq

HERPETIC

Valtrex	faq
Famvir	faq
Zovirax	faq
Acyclovir	faq

SMOKING

Zyban	faq

Viagra **Phentermine** **Levitra**

$60 $60

Soma **Ambien** **Tramadol**

$60

Welcome to [redacted]. Now you can order your medications online and have them delivered to your doorstep overnight.

After you submit your order, one of our U.S. licensed physicians will review your request and issue a prescription for your medication. Next, our U.S. Licensed Pharmacy will ship your order discreetly, via Fed-Ex. This is the fastest , most convenient and least costly way to order prescription medications.

If you have any questions, the best way to reach us is via email, by clicking on "Contact Us" at the top . You can also call us toll-free at .

We look forward to serving you and becoming your source for overnight delivery of all your prescription medications.

INJECTIBLES

Growth Hormone	faq
HCG	faq
Nolvadex	faq

ALLERGY RELIEF

Claritin	faq
Allegra	faq
Flonase	faq
Nasacort	faq
Nasonex	faq
Zyrtec	faq

FEMININE

Diflucan	faq
Orthoevra	faq
Orthotricyclen	faq

PAIN RELIEF

Buspar	faq
Ultram	faq
Celebrex	faq
Vioxx	faq

STOMACH

Nexium	faq
Prilosec	faq

MOTION SICKNESS

Transderm	faq

GENITAL WARTS

Aldara	faq

DEPRESSION

Prozac	faq
Zoloft	faq
Paxil	faq

MIGRANE & HEADACHE

Esgic	faq
Imitrex	faq

DIAPER RASH

Tushbalm	faq

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	Nexium™	40 mg	30 tablets	$189	$119.95	37%	BUY NOW
	Paxil™	20 mg	30 tablets	$189	$119.95	37%	BUY NOW
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	Viagra™	100 mg	30 tablets	$399	$179.95	56%	BUY NOW
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Mr. WAXMAN. The growing number of illegitimate Internet pharmacies has alarmed State medical boards. Yet States which traditionally have regulated the practice of medicine and pharmacy have been frustrated in their ability to shut these sites down. One problem is that enforcement efforts are complicated. A Web site operator can be in one State, the pharmacy in a second State and the prescribing physician in a third State. This may bring three different State standards into play.

A second problem is that even when they are successful, States typically can only obtain an injunction that keeps an illegitimate site from selling to residents of that State alone. And a third problem is that some State laws are too vague to allow boards of medicine and pharmacy to quickly crack down on these illegitimate sites.

When States cannot solve a national problem, it is essential that the Federal Government step in. In this case, however, the Department of Health and Human Services has been reluctant to venture into an area traditionally handled by the States absent clear direction from Congress. It's now time for Congress to provide that clear direction. Last year, this committee held an investigative hearing examining domestic Internet pharmacies. At the hearing, individuals representing State and medical pharmacy boards expressed support for legislation that would create a Federal definition of valid prescription for the purposes of Internet prescribing.

The Chief of Enforcement at the Food and Drug Administration testified that such a standard would assist his agency with shutting down illegitimate sites. And the chairman of the Federal Trade Commission described a successful model in the Federal Telemarketing Sales Act that permits States to work with the Federal Government to protect consumers.

Since that hearing, we've worked together, Chairman Davis and I, to craft a narrow, but effective legislative remedy. Our bill, H.R. 3880, creates a single national standard for valid prescription for Internet prescribing, by barring Web sites from arranging prescriptions from doctors who have never seen the patients. It also provides that Internet pharmacies make basic disclosure of information to consumers, and it allows State attorneys general to obtain nationwide injunctions against illegal sites, avoiding the need for cumbersome State by State enforcement.

Our philosophy with this bill is that less is more. We have aimed to define the minimum Federal standard necessary to accomplish our goal, and we have encouraged enforcement by the States, the traditional regulators of medicine and pharmacy. Our bill does not affect the separate question of reimportation of prescription drugs, and it would not alter the practice of telemedicine.

I look forward to hearing from the distinguished witnesses today and to working with Chairman Davis and all the members of this committee to improve this bill as necessary and move it through the Congress. This is a good example of the legislative process at its finest. After hearing from the witnesses at our first hearing on the matter, we looked at what they had to say, we heard what they suggested and we came up with a proposal. Now today we'll hear reactions to these proposals. Those reactions and the input help us make sure that we're working together on a bipartisan basis to

make the bill as good as it possibly can be to protect the public interests.

I thank the chairman for setting the tone and working in this way so that we can accomplish something that's important for the American people.

Chairman TOM DAVIS. Thank you, Mr. Waxman.

Do any other members wish to make statements? The gentlelady from the District of Columbia.

Ms. NORTON. Mr. Chairman, I appreciate the way you and Ranking Member Waxman have worked together to try to deal with this relatively new phenomenon. It is also a new phenomenon in our society that prescription drugs are advertised on the media. In fact, some of the advertisements are truly laughable. After trying to entice you to, in this country I suppose, go to your doctor and get a prescription for XYZ drug, then they list all the things it will do to hurt you. I guess that's because of regulations of the FDA. So they become fodder for the late night talk shows, all these miracle drugs are advertised along with all the things they could do to harm you, so there will not be liability, in case you don't understand that these drugs have both good and bad effects.

But of course, if you go to your doctor, you're going to find that out, and you're going to have a professional that makes that judgment and advises you accordingly. But the Internet has opened up a straight line path between the patient and somebody somewhere who in fact will provide this drug that perhaps you have seen on television that you think is exactly what you need to do what you want, without any expert intervention. This, I cannot, first of all, it amazes me that this has gone on this long without some action at the Federal level. I understand that States have tried to do something about this. But this of course cries out for ICC, for the commerce clause intervention of the Federal Government.

I say that I'm surprised that no catastrophe has occurred with people ordering these drugs. I'm sure there has. If problems have occurred, I can't imagine where the liability would lie, or if in fact you would find somebody to sue and sue successfully, especially since this goes on across international boundaries. This has already gone on much too long. We have no way of knowing, no way of knowing how many people have been hurt. We do know this is a very enticing temptation, particularly when the drugs are advertised on legitimate television and you can eliminate some of the difficulties, especially with the cost of health care, and going to a doctor, by going straight to one of these Web sites and perhaps doing yourself great harm.

Prescription drugs are the true miracle medicine for today, because they do so much good, I think the time has come to make sure we don't besmirch what these drugs can do by allowing this matter to hang out there unattended. I thank you very much again, Mr. Chairman, for this hearing.

Chairman TOM DAVIS. Thank you. Any other statements?

If not, we have our first panel. We have Mr. William Hubbard, who is here testifying on behalf of the Food and Drug Administration. Mr. Hubbard is the Associate Commissioner for Policy and Planning. He is accompanied by Mr. John M. Taylor, III, the Asso-

ciate Commissioner for Regulatory Affairs. Mr. Taylor will be available to respond to questions posed by Members.

It is the policy of this Committee to swear in all witnesses before they testify. Would you stand with me and raise your right hands?

[Witnesses sworn.]

Chairman TOM DAVIS. Thank you.

Mr. Hubbard, your entire statement is a part of the record. What we would like you to do is try to keep it to 5 minutes. We have a light in front of you, when it turns orange, it means 4 minutes are up and when it turns red 5 are up, and try to move to summary, because our questions are based on your entire testimony.

We welcome you and thank you for being with us. You too, Mr. Taylor.

STATEMENT OF WILLIAM K. HUBBARD, ASSOCIATE COMMISSIONER FOR POLICY AND PLANNING, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY JOHN M. TAYLOR III, ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION

Mr. HUBBARD. Thank you, Mr. Chairman. As you say, I do have a written testimony.

I will just make a few brief remarks. We thank the committee for holding this hearing. We believe you are recognizing a significant public health threat from unregulated Internet sites. The Internet sales of drugs are a wonderful tool for pharmacists and patients and physicians to use. However, only when they're properly operated and regulated, and as you are pointing out, many of these are not.

The public health threat, we believe, is real when patients unknowingly purchase these drugs from unknown Web sites. And the disclosure concept that you have recognized we believe is an important one.

We appreciate that the committee is trying to identify some solutions to this problem, who and where these sites are, whether they are licensed, whether they use one of these dubious questionnaires. The concept of the intermediary is clearly very important in the prescribing of drugs, and these sites often do skirt that.

FDA often monitors the Internet, and one of the sites that we've just noticed very recently I'd like to point out to the committee, if I could ask the clerk to bring it up to the Chair. This site is quite interesting, because we believe it is emblematic of some of the things that your bill is attempting to do and the committee is recognizing.

As speakers on the committee pointed out, many Americans get e-mails offering to sell prescription drugs. This particular site, and there's a poster of it over here against the wall, offers to sell generic drugs. These particular generic drugs or alleged generic drugs do not have generic versions. So we decided to investigate that a bit more.

So we did a check on the location of the actual Internet site and found that it was in China, in Xiandong Province, China. We thought they might be selling Chinese counterfeits. So we actually made a purchase. When the drug arrived, as you'll see on the envelope there, it has a return address of Miami, FL. Yet the postmark,

you may notice, is Dallas, TX. Then there's a return address, if someone needs to reorder, in the package that suggests that the person should contact someone in the country of Belize. Then there's an 800 number which we called, and the person there said they were located in the United States. When we called back a second time, they said they were in Belize.

We ordered three drugs, Ambien, a controlled substance, it's a sleep aid, Viagra and Lipitor. And we noted on the so-called online questionnaire that we were taking erythromycin. Erythromycin is a drug that's contraindicated for Lipitor. So here you have the kind of situation the committee is pointing out, you've got a so-called questionnaire in which the patient has a consultation with some potential physician in another country, and you've got a lack of disclosure, and in fact, this site has so many convoluted potential sources that we don't know where it is.

So the disclosure concept that is embodied in the bill we believe would address these sorts of issues of the sites not being where anyone knows about, and allowing people to buy or get a drug that has no true prescription with it, there's not really a doctor at the other end that sees the patient, diagnoses the patient and makes a rational prescription for the patient.

So with that, Mr. Taylor and I will be happy to take questions.

[The prepared statement of Mr. Hubbard follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

WILLIAM K. HUBBARD

ASSOCIATE COMMISSIONER FOR POLICY AND PLANNING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

HEARING ON

INTERNET DRUG SALES

March 18, 2004

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Committee, I am William K. Hubbard, Associate Commissioner for Policy and Planning at the Food and Drug Administration (FDA or the Agency). John M. Taylor, III, Associate Commissioner for Regulatory Affairs at FDA is here with me. We are pleased to have this opportunity to discuss our continuing mutual concerns about the benefits and risks of pharmaceutical sales over the Internet and what the Agency has been doing to address issues related to the sale of drugs from foreign sources.

With greater and greater frequency, consumers are using the Internet to access health related information and products. Sales of consumer products over the Internet have grown rapidly, including the sale of drugs. The growth in online drug sales by reputable pharmacies has provided significant benefits to consumers. Many managed health care organizations are searching for ways to achieve cost savings and are turning to online prescription plans as a means of providing quality service at a lower cost.

A number of online drug websites, however, present risks to purchasers and unique challenges to regulators, law enforcement officials and policy makers. FDA is concerned about the public health implications of Internet drug sales, and we are responding to these concerns as we develop and implement risk-based strategies to protect the public health. FDA monitors the Internet to evaluate the quality of products and information being offered, and we encourage consumers to remain vigilant about their purchases and to rely on reputable Internet sites.

FDA remains concerned about consumers directly purchasing foreign unapproved drugs through the Internet, because of the Agency's continued concerns that there is not sufficient information or means to assure that these products are as safe and effective as products sold within the United States. But this testimony also focuses on issues related to the purchase of prescription drugs from domestic websites. In this statement, we will discuss the advantages and risks of online drug sales, outline FDA's authority and enforcement activities in this area, and describe initiatives we are taking to better respond to the regulatory challenges we face.

In the context of prescription drug sales over the Internet, the private sector also has an important role in promoting consumer education and in providing assurances to consumers about the quality of products and services they offer. Our challenge is to make sure that the protection for consumers who purchase prescription drugs in cyberspace is just as strong as the protection consumers enjoy when they purchase drugs at their corner pharmacy. Rapid technological developments have magnified the challenges we face. As electronic commerce embraces global markets, we need to acknowledge the need to assure safety and effectiveness regardless of the jurisdiction in which a U.S. consumer resides or the location of the pharmacy.

BENEFITS OF ONLINE DRUG SALES

The Internet is rapidly transforming the way we live, work, and shop in all sectors of the economy. In the health sector, telemedicine allows people in remote areas to access the expertise of doctors in the nation's finest health centers. The Internet permits individuals to obtain extensive medical information to help them understand health issues and treatment options.

Millions of Americans used the Internet last year to find medical information, either in documentary resources or through online discussions with health professionals. Conducting research regarding health concerns is the sixth most common reason that people use the Internet, according to the market research firm, Cyber Dialogue Inc.

The sale of most consumer products over the Internet has grown rapidly in recent years, including the sale of prescription medications. Prescription drug sales over the Internet can provide tremendous benefits to consumers. These benefits are many and include:

- Access to drugs for the disabled or otherwise homebound, for whom a trip to the pharmacy can be difficult;
- The convenience of shopping 24 hours a day; and a wide selection of pharmaceutical products;
- Privacy for those who don't want to discuss their medical needs in a public place.

FDA is aware that many reputable Internet pharmacies provide consumers seeking prescription drugs with a measure of safety, privacy and convenience. They can provide detailed information on drug interactions, and may e-mail customers if the drug they ordered has been recalled, a cheaper generic version of the drug becomes available or to remind them of prescription renewals. Some also sell drugs for less than traditional "brick-and mortar" pharmacies. Hyperlinks and search programs provide online customers with written product information and references to other sources of health information more easily than in the traditional storefront. Finally, as the use of computer technology to transmit prescriptions from doctors to pharmacies expands, a reduction in prescription errors may be possible.

While online pharmaceutical sales are important for some customers, brick and mortar pharmacies can offer benefits and services that are often not available through the Internet, such as quick access to prescription drugs needed for immediate treatment. These pharmacies will undoubtedly remain an essential component in the delivery of effective health care.

In matters relating to pharmaceutical sales over the Internet, the challenge for government at both the state and Federal level is to develop and implement policies that will allow legitimate electronic commerce to flourish while continuing to assure safety and efficacy of these products. Consumers must have confidence that safeguards for online consumers are as least as protective as those at brick and mortar pharmacies.

CONCERNS ABOUT ONLINE DRUG SALES

As beneficial as this technology can be, the Internet also has created a marketplace for the sale of unapproved drugs, prescription drugs dispensed without a valid prescription, or products marketed with fraudulent health claims. Consumers may have difficulty identifying which sites sell legitimate products. As FDA considers the issues related to online drug sales, we recognize that there are various types of websites engaged in drug sales. Many sites focus on selling prescription drugs and are referred to by some as "Internet pharmacies." These sites offer for sale either FDA-approved prescription drug products, or in some cases, unapproved, illegal versions of prescription drugs. While Internet sites operated by legitimate, properly licensed pharmacies provide genuine benefits to consumers, sites that are unlicensed or otherwise

engaged in the illegal dispensing of prescription drugs pose a serious potential threat to the health and safety of American citizens. In many cases, FDA cannot provide consumers with assurance that the drugs purchased over the Internet were manufactured under current good manufacturing practice (cGMP) requirements, even if the website appears to be based in the U.S. While the increase in "Internet pharmacies" engaged in illegal sales is seen as a potent threat, FDA believes that some of the non-pharmacy sites are also harmful. We have moved aggressively against these types of sites that unlawfully offer unapproved drug products, products making fraudulent health claims, or drugs for recreational use.

Patients who buy prescription drugs from an illegitimate site are at risk of suffering adverse events, some of which can be life threatening. These risks include potential side effects from inappropriately prescribed medications, dangerous drug interactions or drug contamination. Patients are also at risk because they often don't know what they are getting when they purchase some of these drugs. Although some patients may purchase genuine product, others may unknowingly buy counterfeit copies that contain inert ingredients, legitimate drugs that are outdated and have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent products that were improperly manufactured.

FDA is concerned about the proliferation of sites that substitute a simple online questionnaire for a face-to-face examination and patient supervision by a health care practitioner. According to the American Medical Association, a health care practitioner who offers a prescription for a patient he or she has never seen before, based solely on an online questionnaire, generally does not meet the appropriate medical standard of care. Four years ago, the Federation of State Medical Boards, Special Committee on Professional Conduct and Ethics found that "Prescribing of medications by physicians based solely on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct." This statement is especially important in light of the primary responsibility of states in regulating the practice of medicine. FDA is concerned that the use of such questionnaires may jeopardize the privacy of a patient's medical records, as online pharmacies may not comply with privacy practices required of entities covered by the Health Insurance Portability and Accountability Act.

The Agency is equally concerned that in some Internet transactions there is an apparent absence of any health professional/patient relationship. This is a particular concern where a patient may be using a prescription drug for the first time or where the patient may be taking other medications. FDA is concerned that the selection of prescription drug products or treatment regimens for a particular patient should be made with the advice of a licensed health care practitioner who is familiar with the patient's current health status and past medical history. In situations where a customary physician-patient relationship does not exist, the patient may be practicing what amounts to self-diagnosis. Consequently, the risk of negative outcomes such as harmful drug interactions, contraindications, allergic reactions or improper dosing is potentially magnified.

Consumers can, and should, be cautious when purchasing drugs online. There are legitimate sites that dispense drugs based on valid prescriptions. Consumers should check with their State Board of Pharmacy or the National Association of Boards of Pharmacy to see if the online pharmacy possesses a valid pharmacy license and has met state quality standards.

One means that consumers have at their disposal to protect themselves is the Verified Internet Pharmacy Practice Sites, or VIPPS system, developed by the National Association of Boards of Pharmacy (NABP) in choosing online pharmacies with which to do business. This program, which verifies the legitimacy of Internet sites dispensing prescription drugs, provides a "seal of approval" to sites that apply and meet state licensure requirements and NABP's standards. Although participation in the VIPPS program is voluntary, the Agency believes this program is an example of one that is very helpful in assuring consumers that the Internet site they are using is reputable.

USE OF THE INTERNET TO BYPASS REGULATION

The unique qualities of the Internet, including its broad reach, relative anonymity, and ease of creating new or removing old websites, pose new challenges for the enforcement of the Federal Food, Drug, and Cosmetic (FD&C) Act and state laws regulating the practice of medicine and the practice of pharmacy. FDA has found that many Internet sites are actually comprised of multiple related sites and links, thereby making investigations much more complex and resource intensive. The global nature of the Internet creates special problems for effective law enforcement. Different approaches to drug approval and marketing in foreign countries further complicate law enforcement issues for U.S. officials. FDA and other U.S. government agencies must try to work with foreign governments to share information and to develop mechanisms for cooperative law enforcement, but this is a difficult task.

FDA Authority

The types of unlawful conduct that can occur when drugs are sold over the Internet are similar to unlawful activities that occur in other contexts. Under the FD&C Act, FDA has the legal authority to take action against:

- The sale, distribution or importation of an adulterated or misbranded drug;
- The sale, distribution or importation of an unapproved new drug;
- Illegal promotion of a drug;
- The sale or dispensing of a prescription drug without a valid prescription; and
- Counterfeit drugs.

When the Internet is used for an illegal sale, FDA, working with the Department of Justice (DoJ), must establish the grounds for a case, develop the same charges, and take the same actions as it would if another sales medium, such as a storefront or a magazine, had been used. FDA has investigated and referred numerous cases for criminal prosecution and initiated civil enforcement actions against online sellers of drugs and other FDA-regulated products, particularly sellers of drugs not approved by the Agency.

State Regulation of the Practice of Medicine and Pharmacy

The states have enacted laws regulating the practice of pharmacy and the practice of medicine to protect patients from harm resulting from the use of unsafe drugs, and the improper practice of

medicine and pharmacy. Under many of these laws, to receive a prescription drug, a licensed health care practitioner who determines the appropriate treatment and issues a prescription for an FDA-approved drug generally must examine a patient. The prescription may also authorize refills. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets state standards.

Even with these Federal and state systems in place, the Internet provides ample opportunities for circumventing established safeguards. The speed, ease, and anonymity of ordering products on the Internet can attract unscrupulous sellers. Individuals not licensed to sell prescription drugs can easily create websites that appear to represent legitimate pharmacies. The fact that operators can quickly change the location and appearance of their Internet site makes enforcement all the more difficult.

State and federal safeguards are not always maintained when drugs are purchased over the Internet. A health care practitioner may not examine the consumer prior to the purchase of drugs online. A patient-doctor relationship may not be established. Unfortunately, attempts to stop some U.S. doctors and online pharmacies from issuing online prescriptions without a physical examination have not always been successful. States face many obstacles when it comes to online pharmacies. State pharmacy and medical boards have limited resources for enforcement and state regulations may not fully address the Internet context. Many states have not yet fully determined how to address the issues that arise from online prescribing.

Jurisdictional Challenges

Online drug sales pose unique challenges for regulatory and law enforcement agencies at the state, Federal and international level. Internet technology can obscure the source of the product as well as provide a degree of anonymity to those responsible for selling and shipping the product. The parties to a transaction can be dispersed geographically and usually never meet. Thus, the regulatory and enforcement issues cross state, Federal, and international jurisdictional lines.

The sale of drugs to U.S. residents via foreign websites is an extremely challenging area. Medications sold on the Internet that may be legal in foreign countries may not be approved for use in the U.S. Products not approved for sale in the U.S. often do not conform to the cGMP and quality assurance requirements in U.S. laws and regulations, and it is illegal for a foreign pharmacy to ship such drugs into the U.S. Foreign sales pose the most difficult challenge for U.S. law enforcement because the seller is not within U.S. boundaries. Although FDA may have jurisdiction over a resident in a foreign country who sells in violation of the FD&C Act to a U.S. resident, from a practical standpoint, the Agency working with DOJ has a difficult time enforcing the law against foreign sellers, when they are hard to reach and outside our borders. As a result, the Agency's efforts typically focus on requesting the foreign government to take action against the seller of the product, or asking the U.S. Customs and Border Protection (CBP) to stop the imported drug at a U.S. port-of-entry.

FDA ACTIONS TO PROTECT PUBLIC HEALTH

FDA has long been engaged in taking steps to minimize the dangers to public health posed by the sales of drugs on the Internet. In July 1999, FDA adopted, and has since been implementing, an Internet Drug Sales Action Plan, which includes five key areas of activity:

- Engaging in public outreach and education;
- Partnering with professional organizations;
- Coordinating action with state and other federal agencies;
- Cooperating internationally; and
- Enhanced enforcement tailored to the Internet environment.

Public Education

FDA's "Buying Rx Drugs Online" education program is a multi-media campaign, which is centered on FDA's website: http://www.fda.gov/oc/buyonline/default.htm, which can be accessed from FDA's home page. The website includes information for consumers, including tips and warnings on how to spot health fraud, frequently asked questions (FAQ's) and where to report suspected "rogue" sites. The page is one of the most frequently visited on FDA's website, and we are currently logging approximately 60,000 complaints a month in the mailbox.

FDA's public outreach includes FDA *Talk Papers*, articles in *FDA Consumer* magazine, and information on FDA's website to help educate consumers about safely purchasing drugs online. FDA's website also provides consumers with an opportunity to submit information to the Agency about sites that may violate the FD&C Act. Another central piece of our campaign is a brochure entitled, "Buying Prescription Medicines Online: *A Consumer Safety Guide*." The brochure was produced by the CybeRx Smart Safety Coalition, a partnership of Internet companies, trade associations, health and consumer organizations and other government agencies. The number of consumer complaints received by FDA has grown steadily with the circulation of the brochure.

Professional Outreach and Partnering

FDA continues to interact with organizations representing state regulatory and law enforcement bodies, consumers, health care practitioners and industry. These cooperative relationships include the following organizations:

- The National Association of Boards of Pharmacy
- The Federation of State Medical Boards
- The National Association of Attorneys General
- The American Medical Association
- The American Pharmaceutical Association
- The National Consumers League
- The American Society of Health-Systems Pharmacists
- The National Association of Chain Drug Stores
- The National Community Pharmacists Association
- Pharmaceutical Security Institute

Coordination with State and Federal Agencies

Several Federal agencies, as well as the states, have the authority to regulate and/or enforce U.S. laws related to the sale of drug products online. Due to the growth of potential cases involving the Internet, there are instances when working with another agency or state yields a more effective enforcement result. Working closely with the states is essential to effectively regulate the sale of drugs, as well as the sale of prescription drugs without a valid prescription over the Internet. FDA has established partnership agreements with several state bodies, including the National Association of Boards of Pharmacies and the Federation of State Medical Boards, to coordinate Federal and state activities aimed at questionable practices associated with the selling and prescribing of prescription drugs over the Internet.

FDA has increased coordination with other governmental bodies and meets regularly with other Federal agencies and state officials to share information, discuss the roles and responsibilities of the parties regarding online drug sales and identify opportunities for partnering in enforcement actions. FDA maintains strong working relationships with the Department of Justice, including the Drug Enforcement Administration (DEA) and Federal Bureau of Investigation (FBI), the U.S. Postal Inspection Service, CBP, the Office of National Drug Control and Policy (ONDCP) and other appropriate Federal and state agencies. FDA believes that cooperation among Federal agencies is particularly critical to address the sale of drugs to U.S. residents by foreign sellers.

FDA is also involved in the effort to combat an increase in the abuse of prescription drugs, which is evident in the increasing illegal sales of controlled substances on the Internet. In announcing the President's National Drug Control Strategy for 2004, ONDCP has brought together the efforts of FDA, federal substance abuse prevention and treatment agencies, and law enforcement to bear on the factors contributing to rising prescription drug abuse. The Strategy incorporates education of medical professionals and consumers, outreach to businesses involved in Internet commerce, pharmaceutical manufacturers, and pharmacies. The new program includes a range of activities designed to reduce the abuse of prescription drugs, and includes the use of web crawler/data mining technology to identify, investigate and prosecute "pill mills" -- Internet pharmacies that provide controlled substances illegally.

In conjunction with DEA, FDA will implement additional investigative efforts and enforcement actions against the illegal sale, use, or diversion of controlled substances, including those occurring over the Internet. Many of these e-pharmacies are foreign-based and expose the purchaser to potentially counterfeit, contaminated, or adulterated products.

Enhanced Enforcement

Since 1999, FDA has aggressively expanded its investigation and enforcement activities relating to Internet drug sales because we believe that illegal online drug sales pose a significant public health risk. FDA has initially focused its enforcement activities in the following areas:

- Unapproved new drugs;
- Health fraud; and
- Prescription drugs sold without a valid prescription.

FDA has increased its capability to monitor the Internet and identify sites that potentially violate the FD&C Act through the use of various search tools and by upgrading its data handling capabilities. These actions help the Agency to better understand the type and extent of unlawful conduct on the Internet and to more accurately assess whether its enforcement efforts have had an impact on illegal behavior. FDA has reviewed thousands of websites and identified hundreds involved in the sale of drug products. But this remains a daunting task and each day new sites are identified.

Since 1999, FDA has reviewed potential enforcement actions and coordinated case assignments through the use of a case assessment or "triage" team with representatives from the Office of Enforcement and OCI within the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Office of Chief Counsel (OCC) and the Office of Policy. Under the triage process, FDA obtains leads on sites that potentially violate the FD&C Act from internal Internet monitoring activity, state, other Federal or foreign law enforcement agencies, consumers, Congress, and the press. The triage team evaluates leads and decides whether they should be pursued through a civil or criminal investigation. Priority is given to cases involving unapproved new drugs, health fraud, and prescription drugs sold without a valid prescription and products with the potential for causing serious or life-threatening reactions. The triage team makes referrals, when appropriate, to various offices within FDA for follow-up.

The triage process results in a better coordination of criminal and civil enforcement actions at the appropriate Agency components and reduces overlapping effort. This process helps to ensure that decisions are made in a timely way. The Agency seeks an appropriate balance in terms of achieving a maximum deterrent effect while taking action, if needed, to remove harmful products from the market. The team will continue to oversee Internet-related enforcement activities while they are being investigated, and will ensure that they are brought to appropriate conclusion.

OCI, working with OCC, is responsible for investigations of pharmacy sites and other Internet drug sites whose operations involve potential criminal activity. The Investigative Analysis Branch analyzes the information collected by OCI. After the suspect sites are researched, and possible violations are identified, the OCI field offices receive assignment for investigative work, which often includes undercover buys. Further investigation determines the bona fides of the pharmacy and doctor(s), and examines the relationship between the patient and doctor and the doctor and pharmacy. OCI has ongoing cooperative relationships with CBP, DEA, FBI, the Postal Inspection Service and appropriate state law enforcement and regulatory agencies, and this has enhanced their investigative capabilities with regard to Internet drug sales.

The following examples of enforcement actions taken by FDA illustrate the serious risks to the public health posed by fraudulent or illegal drug sales utilizing the Internet.

Counterfeit Contraceptive Patches

On February 4, 2004, FDA issued a warning to the public about a foreign Internet site selling counterfeit contraceptive patches. These counterfeit patches contain no active ingredients and therefore provide no protection against pregnancy. The Internet site, www.rxpharmacy.ws,

apparently is operated by American Style Products of New Delhi, India. On February 12, the Agency took action against three additional Internet sites associated with sales of the counterfeit patches -- www.usarxstore.com, www.europeanrxpharmacy.com, and www.generic.com. FDA obtained the cooperation of the U.S.-based Internet service provider (ISP) in shutting down service to these websites. FDA/OCI is working with the manufacturer and other federal agencies to further investigate the matter.

The counterfeit contraceptive patches were purported to be an FDA-approved product,. Instead, customers receive packages of patches without the active ingredient necessary to make the patches effective. Moreover, the counterfeits were sent in simple plastic zip-lock bags without identifying materials, lot numbers, expiration dating or any other labeling information needed to safely and effectively use this prescription product.

Photos contrasting the legitimate contraceptive patch with the counterfeit are displayed on FDA's website. Women who have been sent contraceptive patches lacking proper labeling or not having the appearance of the approved product as described above should not use the product and should contact their healthcare providers immediately.

These websites also sold other products that purport to be versions of FDA-approved drugs. FDA is investigating these other products as well, and we urge consumers to treat any drugs purchased from this firm as being suspect. None of these products should be considered safe or effective. Additional information about the counterfeit contraceptive patches is attached as Appendix C.

Genapharm.com

On March 9, 2004, Hadi M. Ghandour, owner of Genapharm, Inc. of Austin, Texas, pled guilty to four counts of conspiracy to introduce misbranded and unapproved new drugs into interstate commerce, counterfeiting human growth hormone, and possessing controlled drugs with intent to distribute. Ghandour admitted to engaging in a conspiracy to sell unapproved, misbranded, counterfeit and Schedule I controlled drugs from 1999 to 2001. Ghandour sold these drugs through Genapharm, Inc. and Bioscultpt Technologies, Inc., and through an Internet website, www.genapharm.com.

The drugs included:

- 1,4 Butanediol, which converts into gamma hydroxybutyric acid or GHB, a Schedule I Controlled Substance, when metabolized by the human body;
- Counterfeit human growth hormone;
- 4 Bromo-2, 5-dimethoxyphenethylamine (2CB or Nexus), a Schedule I Controlled Substance;
- BZP, which if combined with 1-(3-trifluoromethylphenyl) piperazine (TFMPP), has stimulant and hallucinogenic effects similar to 3,4-methylenedioxymethamphetamine (MDMA), or ecstasy, a Schedule I Controlled Substance; and
- Tiratricol, tri-iodothyroacetic acid (TRIAC), a potent thyroid hormone.

Two other persons involved in these offenses were previously convicted and sentenced. Ghandour faces up to five years in prison and a fine of $250,000 on each count. The

investigation was conducted by FDA/OCI and the DEA, with assistance from the Dallas District Office of the FDA and the Texas Department of Health.

Rx Clinic

On December 3, 2003, a 108-count indictment charging ten individuals and three companies with illegally selling controlled substances and other prescription drugs over the Internet was unsealed. The indictment charges that the defendants used an "online ordering process" to allow consumers to order prescription controlled substance drugs over the Internet, through such websites as "www.get-it-on.com," without ever seeing a doctor. Defendants were charged with, among other things, conspiring to unlawfully distribute Schedule III and IV controlled substances (including weight-loss drugs Bontril, Ionamin, Phentermine, Adipex, and Meridia) without a legitimate medical purpose and outside the usual course of professional practice. Defendants include Vineet (Vincent) K. Chhabra of Florida, an owner, operator, and officer of the businesses, and Sabina S. Faruqui of Florida, an officer, manager, and operator of the businesses. Also indicted were five physicians, a pharmacist, and a partner of Chhabra's who co-owned and operated some of the websites. Various defendants are charged with money laundering, and the indictment seeks forfeiture of $125 million. Several defendants are charged with violating the FD&C Act by introducing into interstate commerce misbranded prescription drugs, including Bontril, Meridia, Xenical, and Viagra.

On December 19, Marvin Brown, a physician, and Luke Coukos, a pharmacist, entered guilty pleas to charges related to this case. Brown, a retired obstetrician-gynecologist, relinquished his DEA controlled substance registration, and turned in his licenses to practice medicine in Ohio and Massachusetts. Brown pled guilty to conspiracy to dispense and distribute controlled substances, and admitted that in the course of the conspiracy he authorized more than 22,056 prescriptions for Schedule III and IV controlled substance diet drugs. Coukos pled guilty to conspiracy to dispense and distribute controlled substances and to introduce into interstate commerce prescription drugs without the prescription of a practitioner licensed by law to administer prescription drugs. Coukos admitted that he personally dispensed at least 43,066 Schedule III and IV controlled substance prescriptions, and at least 9,055 prescriptions for non-controlled prescription drugs. Coukos was sentenced on March 12 to 60 months' incarceration and a $140,318 fine.

Kwikmed

On October 1, 2002, a Federal Grand Jury in Arizona returned a 198 count indictment against Kwikmed, Inc., Cymedic Health Group, Inc., four owners of these corporations, and two physicians associated with the corporations. The indictment alleges that defendants operated Internet websites, two of which include Kwikmed.com and Cymedic.com, through which they sold prescription drugs, including Viagra, Celebrex, Xenical, and Propecia. The websites did not require a consumer to have a prescription before receiving the drugs. Instead, the customers were required to complete a questionnaire, which the website told customers would be reviewed by a physician.

Customers were charged a fee for this purported medical consultation. The indictment alleged that in the overwhelming majority of applications, no medical reviews, consultations, or physical examinations by a physician took place before drugs were shipped to customers. The defendants repackaged drugs obtained from a drug wholesaler, even though they were not a registered manufacturer or a licensed pharmacy and there was never a licensed pharmacist involved. The drugs dispensed were adulterated because of the defendants' failure to follow cGMP in packaging, holding, and labeling of the drugs.

The indictment alleged that during the course of the conspiracy the defendants and others generated sales in excess of $28 million that was billed to consumers as charges for prescription drugs, doctor consultations, and shipping. The indictment charges defendants with violations of the FD&C Act, as well as conspiracy, mail fraud, and money laundering. The charges were the result of an investigation by FDA and the U.S. Postal Inspection Service.

On October 2, 2003, William J. Clemans, a physician, pled guilty to five felonies for his involvement with these Internet websites. In his plea, Clemans admitted that generally a physician did not review questionnaires before drugs were shipped to customers. Charges to which Clemans pled included: 1) conspiracy, 2) introduction of misbranded drugs into interstate commerce, 3) failure to register a drug manufacturer, 4) mail fraud, and 5) conspiracy to commit money laundering. Clemans also agreed to forfeit $600,000.

On December 16, 2003, Adalberto Robles Guzman, a physician also charged in this case, entered a guilty plea to two felony counts for tax evasion. In the plea agreement, Robles admitted he omitted from his tax return over $100,000 of income received from Kwikmed. A third defendant, Janice Gamblin, one of the owners of Kwikmed, Inc., pled guilty this month to conspiracy, introduction of misbranded drugs into interstate commerce, mail fraud, money laundering and failure to register an establishment in which drugs are manufactured; prepared; propagated; compounded; and processed.

Norfolk Men's Clinic

On February 16, 2002, a federal jury in Alabama convicted Anton Pusztai and Anita Yates of charges arising out of the operation of an online pharmacy that illegally sold prescription drugs over the Internet to consumers. On June 18, 2002, Pusztai and Yates were sentenced respectively to more than 15 and 6.5 years in prison. Pusztai, an Australian citizen, and Yates, a resident of Clanton, Alabama, were convicted of conspiracy to commit violations of the FD&C Act, conspiracy to commit money laundering, mail fraud, dispensing misbranded drugs, and operating a drug repackaging facility not registered with FDA.

From fall 1998 to the summer of 2000, the defendants operated a website called Viagra.au.com, also known as Norfolk Men's Clinic, and related sites, that sold a variety of prescription medications. The case has been appealed to the Eleventh Circuit and is awaiting a decision. This case was investigated by FDA/OCI with assistance from State and local law enforcement.

Storefront Pharmacies

FDA has taken recent actions against so-called "storefront pharmacies," which are generally walk-in businesses, sometimes associated with Internet sites, which assist U.S. consumers in ordering prescription drugs from Canadian or other foreign pharmacies and facilitate the filling of these orders. FDA is concerned about these domestic operations that are not properly licensed under state pharmacy laws, and expose consumers to a number of potential risks. As of November 2003, twenty-two states have taken, or are prepared to take, regulatory actions against storefront pharmacies that facilitate illegal imports of prescription drugs from Canada.

Rx Depot Inc.

The Department of Justice and FDA filed an injunction on September 11, 2003, to stop Rx Depot Inc. from causing the importation of prescription drugs from Canada in violation of U.S. law. The Agency brought the suit because the storefront chain posed a risk to public health by importing unapproved prescription drugs and drugs that may only be imported by the U.S. manufacturer. Earlier in the year, FDA issued a warning letter to Rx Depot in conjunction with the Arkansas State Board of Pharmacy, but the company's response was inadequate. These drugs posed a public health risk because they do not have the same assurance of safety and efficacy as drugs regulated by FDA. Rx Depot and similar companies have incorrectly stated that FDA condones their activities and that their prescription medications are "FDA approved."

On November 6, 2003, U.S. District Judge Claire Eagen granted the government's motion for a preliminary injunction and ordered Rx Depot to stop importing drugs and stop advertising and promoting any service that causes or facilitates drug imports. FDA, and the District Court Judge, concluded that operations such as Rx Depot expose the public to significant potential risks associated with unregulated imported prescription medicines.

CanaRx

On September 16, 2003, FDA issued a warning letter to CanaRx notifying the firm of our concerns about supplying prescription drugs from unregulated sources and making unwarranted claims about these products. Specifically, FDA's warning letter stated that CanaRx runs an Internet website and mail operation that illegally causes the shipment of prescription drugs from a Canadian pharmacy into the U.S., thereby exposing U.S. consumers to risky imported drug products. This potential risk is compounded by the fact that CanaRx makes misleading assurances to consumers about the safety of its drugs.

An FDA investigation of this firm showed that CanaRx operates a drug purchasing arrangement that channels drugs through companies that are not U.S. licensed pharmacies and does not consistently use shipping practices necessary to ensure its drugs are safe and effective. For example, FDA has evidence demonstrating that CanaRx shipped insulin, a product that should be stored under refrigerated conditions, in a manner that did not satisfy the storage conditions specified in FDA approved labeling, which could genuinely compromise the safety and

effectiveness of the insulin. CanaRx's response to the Agency's warning letter was inadequate, and on November 6, 2003, FDA sent a second letter reiterating our concerns about the potential safety of the product, and the firm's business practices. The investigation is ongoing.

Expedite-Rx, SPC Global Technologies, and Employer Health Options

On January 22, 2004, FDA issued a warning letter to Expedite-Rx, a technological interface, SPC Global Technologies, Ltd., a pharmacy benefits manager, and Employer Health Options, Inc., a pharmacy benefits manager, all of Temple, Texas, notifying them that it considers their drug import program to be illegal and a risk to public health. The letter accuses the firms of facilitating illegal imports of prescription drugs from Canada and misleading the public about the drugs' safety. Expedite-Rx, which does not hold a Texas Pharmacy license, was directed by the Texas State Board of Pharmacy last July to "immediately discontinue receiving/processing prescription drug orders." FDA has reviewed the three firms' responses to the Warning Letter and has requested further information from those firms.

Internet Sales Facilitators

Last fall, the popular Internet search engines Google and Yahoo, as well as Microsoft's MSN website announced that they will stop accepting advertising from unlicensed pharmacies. America Online Inc. has said it has restricted sales of illegal drugs beginning approximately two years ago.

Increasingly over the last few years, search engines have become cluttered with links to rogue Web sites. Consumers merely type in a drug name and are linked to an array of Web sites selling prescription drugs, including controlled substances. Unlicensed pharmacies selling narcotics and other prescription drugs pay Internet search engines to link their advertisements to keywords typed in by those who use the search engines. Many of these drug sellers are located offshore and many sell prescription drugs without a valid prescription.

The Agency has strongly encouraged online search engines and other advertising outlets to assist in identifying and removing access to illegitimate pharmacies. The Agency has been in contact with search engines to provide information and assist them in understanding the effect on public health of accepting such advertising.

As these actions indicate, FDA intends to work closely with its partners in the individual states in support of their efforts to curtail illegal and potentially dangerous operations, especially when they involve misleading claims about drug safety. FDA has been working closely with states and private sector entities like the online search engines to address the problem of illegal Internet pharmacy issues over the past four years to protect the public health.

CONCLUSION

Mr. Chairman, online shopping for pharmaceutical products clearly provides many benefits for consumers, but it also poses a number of serious potential risks. The nature of Internet technology presents law enforcement and policy makers with unique challenges. FDA is

grappling with these challenges, and we must strive to carefully balance consumer access to information and products with protecting the public health. We are aggressively using our existing educational, compliance and enforcement tools to combat the proliferation of unsafe or fraudulent pharmaceuticals on the Internet, and we will continue to evaluate what changes in our procedures, regulations, or the law might be appropriate to enhance our efforts. Our goal is to ensure that the protections afforded to consumers who purchase drugs from their corner drugstore also extend to consumers in the electronic marketplace.

We want to work with you and other members and committees that have an interest in this important issue, and I would be happy to answer any questions you may have.

Chairman TOM DAVIS. Thank you very much. I apologize, the vice president was on the phone and I had to have Ms. Harris ably take the Chair while I was there. I apologize for leaving in the middle of your testimony. I did read it last night, though.

Let me start the questioning. Historically, States have been the primary enforcement authority with respect to the practice of medicine and the dispensing of prescription drugs. How do you find that appropriate balance? And of course, the Internet raises a whole new paradigm for us in terms of how you do this, because it's so ubiquitous.

Mr. HUBBARD. And many people have pointed out, because the Internet crosses State lines, it's more difficult for States to enforce in these kinds of cases you have pointed out. Congress has given FDA the authority to regulate the practice of medicine in only one case that I'm familiar with. And the FDA itself has been reluctant to step into the regulation of the practice of medicine, which has been a State responsibility. Here you are identifying the potential need, perhaps, to take one more step into that with the definition of a valid prescription. And we certainly understand your thinking in doing so.

Chairman TOM DAVIS. Both the AMA and the FSMB have guidelines that stipulate an appropriate medical relationship between the patient and physician must exist before a prescription is written and dispensed. AMA and the FSMB define this relationship to include a documented patient evaluation, including medical history and a physical examination.

Do you agree these recommendations are also consistent with the language in H.R. 3880?

Mr. HUBBARD. I believe they are, Mr. Chairman.

Chairman TOM DAVIS. Mr. Taylor, do you agree with that, too?

Mr. TAYLOR. Yes.

Chairman TOM DAVIS. Mr. Taylor, at the hearing last March, you stated that a Federal standard for what constitutes a valid prescription would aid enforcement capabilities. Are you still of that opinion?

Mr. TAYLOR. I did acknowledge that. To put it in context, I think what I said last year was, a part of the complementary enforcement role of the States and Federal Government, we were often relying upon the State medical boards or boards of pharmacy to inform us what the proper standard of medical care is within a particular State. So when we're building a case and there are differences from State to State, that raises some challenges, absolutely.

Chairman TOM DAVIS. FDA has indicated, in your testimony, that it has the legal authority to take action against the sale of dispensing a prescription drug without a valid prescription. How often has the FDA used this authority to take action against rogue Internet pharmacy sites?

Mr. TAYLOR. I can give you a recent example. Yesterday, we announced that we had brought indictment against an Internet pharmacy site, where indeed one of the charges was the fact that the product was being dispensed in a manner that was outside the proper standard of care, standard of medical care and the standard of pharmacy in that particular State.

It's often an element of our criminal cases, what we will do is consult with the States, figure out what the standard is within that State and make that one of the charges. What we've seen in many cases, especially two recent criminal cases, is that there often have been attempts by those who have been indicted to either hide the identity of those physicians that are supposed to be giving proper care, or misrepresenting the fact that they are licensed within a State, when in actuality they are not.

So it's often a component of the cases that we bring.

Mr. HUBBARD. And Mr. Chairman, while we can do in some States that have explicit laws, there are many, many States, in fact the majority of States, where the State law does not explicitly define it in a way that FDA can use its authority.

Chairman TOM DAVIS. Mr. Taylor, also in the March hearing, you noted that you couldn't name a single State that qualifies the use of an online questionnaire as a legitimate or appropriate medical relationship. Do you agree that online medical questionnaires don't constitute an adequate or appropriate medical relationship?

Mr. TAYLOR. Let me refine that answer. I'm aware of approximately 27 States that generally disallow Internet prescribing. I think 7 of those States do so by explicit statute, I think 12 do so based on medical board policy, and another 8 do so based on medical board rulings. There are another 13 States that have chosen to make a determination that Internet prescribing is impermissible.

So now there are approximately 40 States that have taken a position that there is some means as to what constitutes proper Internet prescribing, and an online questionnaire falls outside that arena. Mr. Chairman, one of the things that's changed in the 5 years that we've been dealing with the Internet is the fact that both on the Federal Government level and the State government level, our statutes did not, quite frankly did not contemplate this type of practice.

As time has gone by, the States have taken steps to address it expressly through the medical boards and through their boards of pharmacy. That's why today we have 40 States that have taken some stance. That has obviously enhanced our enforcement efforts on the Federal level, too. So things have changed a little since last year.

Chairman TOM DAVIS. AMA's testimony today highlights the need for something to be done at the Federal level to address the myriad problems associated with the illegal use of Internet pharmacies. Do you agree with them?

Mr. TAYLOR. Well, I mean, traditionally the regulation of, or what constitutes a proper medical standard or what constitutes a proper or valid prescription is something that has resided at the State level. I think to the extent that there is going to be any change in that position, it needs to be done very carefully.

Chairman TOM DAVIS. OK. Thank you very much.

Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. Hubbard, in your written testimony today, you expressed FDA's concern about the proliferation of sites that substitute a simple online questionnaire for a face to face examination and patient supervision by a health care practitioner. Let's assume for the mo-

ment that some of these Web sites employ licensed physicians to write the prescription on the basis of the questionnaire.

When assessing whether these prescriptions are valid, does FDA rely on a single Federal definition or defer to the States?

Mr. HUBBARD. We defer to the States.

Mr. WAXMAN. Are all State definitions alike?

Mr. HUBBARD. No, they are not, Mr. Waxman.

Mr. WAXMAN. Do the varying definitions complicate enforcement actions?

Mr. HUBBARD. No question.

Mr. WAXMAN. H.R. 3880 would solve this problem by creating a single national standard for what is a valid prescription related to Internet pharmacies. We're going to hear from the Virginia State Attorney General on behalf of the National Association of Attorneys General and the Federation of State Medical Boards and the National Association of Board of Pharmacy are going to endorse such a standard.

Why do you think these key State organizations support having a single Federal standard for prescription related to Internet prescribing?

Mr. HUBBARD. When the Internet emerged as a tool of this nature, drug prescribing became obvious at that time. I believe the States thought they could, using their existing authority over physicians and pharmacies, appropriately regulate these businesses.

They realized fairly quickly, I think by the year 2000, that because these sites would be located in one State but the patient in another that they would be unable to do so, and you needed, in their view, and I believe they will express that for themselves, as I understand it, they expressed the view that you needed some sort of a more uniform national standard. I believe they are supportive of that today.

Mr. WAXMAN. So it seems that a single national standard is needed to address these rogue Web sites?

Mr. HUBBARD. It's certainly their opinion.

Mr. WAXMAN. Our legislation provides this standard, while maintaining the key enforcement role for the States, as you well know. Thank you very much for your testimony, both of you, and thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you very much. Mr. Shays.

Mr. SHAYS. I'll pass, thank you, Mr. Chairman.

Chairman TOM DAVIS. Any other questions on this side? The gentleman from Tennessee.

Mr. DUNCAN. Mr. Hubbard, as the chairman pointed out in his first question, the primary enforcement role for prescribing drugs is up to the States. But of course, the Internet does not recognize State lines or moves across State lines, so it's a difficult thing for States to enforce this totally.

I'm just curious, how fast are these Internet prescriptions growing? Do we have any estimate of that? All the articles you read, they say it's growing very fast. But I just wondered if you have any statistics of how many prescriptions are being issued over the Internet now.

Mr. HUBBARD. There's no certainty here. There are clearly estimates made by various groups. I think the National Association of

Boards of Pharmacy has recognized at least 200. There are many more foreign sites. We did a computer search just last week for one particular set from one country, and this is the list. There's well over 1,000 here. And that's just one locality. So worldwide, there may be——

Mr. DUNCAN. Is that 1,000 prescriptions?

Mr. HUBBARD. It's 1,000 different Web sites offering to sell drugs in the kinds of ways that the committee is recognizing.

Mr. DUNCAN. I see. And do you know of instances where children have been getting these drugs over the Internet? Have you heard about that?

Mr. HUBBARD. Certainly there are drugs that children used being prescribed. There's a wide, wide range of drugs being prescribed. Some sites limit themselves to just a few lifestyle drugs like Viagra, but many sites sell a list of hundreds of different drugs.

Mr. DUNCAN. Have you been getting reports of people who have been injured or been hurt or made sick or have been ripped off by these prescriptions?

Mr. HUBBARD. We do have reports. Unfortunately, they are relatively sporadic. They depend on a patient who's injured reporting to us. There's no good system for tracking some of these drugs that are sold illegally. Because the medical system is designed to track systems that are properly prescribed and dispensed by licensed pharmacies in the United States.

Mr. DUNCAN. I know it's difficult, but have you had 100 instances or 1,000?

Mr. TAYLOR. I can't give you a number, but I can give you a tangible example. Last summer, and the agency is continuing to investigate this, but last summer we had to assist in the recalling of over 200,000 bottles of Lipitor, because we discovered that it had been counterfeit. Obviously the benefit——

Mr. DUNCAN. Where was that?

Mr. TAYLOR. I'm sorry?

Mr. DUNCAN. Where was that you recalled——

Mr. TAYLOR. Actually, by the time the recall was finished, the counterfeit Lipitor had spread throughout the country. In some cases it was available through a brick and mortar pharmacy, but in other cases it was available over the Internet. The reason I used it as an example is because obviously the benefit of Lipitor is its cholesterol lowering properties. And one of the——

Mr. DUNCAN. Was that Lipitor being sold by one Internet site or many?

Mr. TAYLOR. It's not clear how many sites it was sold over, but we did get consumer complaints suggesting that it was at least sold over two. What happened is when we put out the original talk paper warning the public about the fact that we had discovered this product, we began to get reports from people. A couple of people reported purchasing it over the Internet.

So I don't know how many Internet sites it was available at, but that's a tangible situation where someone was purchasing a product thinking they were getting cholesterol lowering properties, and because of the nature of the product, not only were they not necessarily getting the cholesterol lowering properties, you could argue

that indeed they were being ripped off, because they were paying for something that they didn't actually get.

Mr. HUBBARD. Let me give you an example, Mr. Duncan. I've got one site here, there are 400 different Web sites, when we checked them, they are all the same business. The same individual runs them, from a small New England town. But they all have different names, and they're targeted at citizens in different countries, Houston, Phoenix, wherever. So the citizen thinks that's a local business in his hometown selling legal American drugs. In fact, it's one business in New England saying 400 times in 400 cities, we're legitimate, we're legal and we'll give you a drug if you'll fill out a questionnaire.

Mr. DUNCAN. OK, well, thank you very much.

Mr. HUBBARD. You're welcome.

Chairman TOM DAVIS. Thank you very much. Ms. Watson, any questions?

Ms. WATSON. I'm waiting on a copy of the bill, Mr. Chairman. But in the bill, this is a question to the Chair, does it require a legitimate prescription from the doctor and how is that checked out? You send this, if there's a requirement by the company, you send that in, how do they check it out to be sure it's valid?

Chairman TOM DAVIS. A valid prescription is required to exist. But we go further to define an adequate medical relationship, so that the person who is prescribing it has done an appropriate examination and taken the history and has had a meeting with the person, as opposed to calling up and a doctor just writing a prescription because you're willing to pay money. That's what's critical in these cases. A lot of these Web sites have people who will sign prescriptions but they know nothing about the people who are taking the drugs, what they're interacting with, and that's where the danger occurs.

Ms. WATSON. Let me ask Mr. Hubbard, certainly each State differs from the other. What would be the standard positions that you would like to see in a piece of legislation that would be able to monitor the abuse of the Internet prescriptions?

Mr. HUBBARD. As Chairman Davis said, FDA has a requirement that there be a valid prescription. That's Federal law.

Ms. WATSON. Yes.

Mr. HUBBARD. But then FDA relies upon each State to determine whether a given prescription in that State is valid.

Ms. WATSON. Who's the watchdog?

Mr. HUBBARD. Well, in the case of prescriptions, it's actually the State medical boards and pharmacy boards, not the FDA. Federal law does have a requirement that there be a valid prescription, but each State then determines what that is.

Ms. WATSON. Question to the Chair, I haven't read the legislation yet. But is there a requirement that each State indicate who the watchdog agency is and what they watch for?

Mr. HUBBARD. I believe it's very clear, Ms. Watson, that the State pharmacy and medical boards have that responsibility. They accept that responsibility. But what they're saying is that they can't utilize their law if the Web site is in another State, because they can't prosecute across State lines.

Ms. WATSON. So how do we at the Federal level get to that issue? That's the crux of this question, and maybe this is to the author.

Chairman TOM DAVIS. What happens in this case is we define an appropriate medical relationship. That's where this stuff goes afoul. They can produce a doctor's note on this, a doctor's prescription, but there's no relationship. It's almost like an auto pen. There is no appropriate medical relationship, as we define the appropriate medical relationship. It would be up to the State and their enforcement actions to go there, and the burden would be on the people who are dispensing this to prove they had the relationship, which of course they don't, in many of these cases.

Ms. WATSON. Who oversees that, the FDA? Or the State attorney general?

Mr. TAYLOR. Just to give you an example, there have certainly been instances where more than one State has recognized behavior that they deemed to be problematic. What the States have been able to do is bring some type of action that is confined to their State boundaries. But what we've also tried to do is work closely with them so that we, the Federal Government, could bring a case that is more global in nature and is complementary to the case that the State is bringing, so there's a more comprehensive approach to dealing with problematic conduct that might be going beyond State lines.

So there is a way to do it.

Chairman TOM DAVIS. Let me try to help you. Our bill allows, the new enforcement authority that we give in this case is modeled on the Federal Telemarketing Sales Act. So we have an appropriate Federal model on this. That allows the State attorney general to shut down a rogue site across the country rather than only bar sales to customers or consumers in his or her State.

Ms. WATSON. If the Internet shows a location down in Central America for controlled drugs, who then is—I see somebody shaking their head—who then is in charge of overseeing that on the Internet?

Mr. TAYLOR. For controlled substances the Drug Enforcement Administration has primarily jurisdiction over controlled substances. However, the FDA and the States will often work, again with DEA, to help bring cases if we determine that those products that are being marketed through the Web site that's listed in Central America are actually making their way to the United States.

Ms. WATSON. May I ask who determines that? How is it triggered? How does the process start?

Mr. TAYLOR. Usually it's triggered based on the working relationships that we've established over the years. We've been at this for about 4 or 5 years. We recognized fairly early on that none of us quite frankly had either the resources or the expertise to do it ourselves. So over the last 4 or 5 years, we've tried to work closely with both our Federal and State partners that we could work together on a real time basis to address these situations when they come to our attention.

So it's really through our partnerships and working relationships. And over time, they've proved to be quite successful. So that's usually how it's done.

Chairman TOM DAVIS. Thank you. Time has expired. Thank you very much.

The gentleman from Connecticut, Mr. Shays.

Mr. SHAYS. Thank you, Mr. Chairman.

Mr. Chairman, thank you and Mr. Waxman for highlighting this issue, thank you for having this hearing, thank you for coming forward with the legislation that we can consider. In my earlier life I used to chair the subcommittee of this full committee that oversaw the FDA. And I appreciate so much what FDA has to contend with.

At the same time, I do have some issues that I want to ask. We talk about the questionnaire that has to be filled out for the Web site. I sent a questionnaire to my constituents. And I had one where I gave a statement, I said strongly agree, somewhat agree, no opinion, somewhat disagree, strongly disagree. This was the statement. Americans should be able to import less costly FDA approved prescription drugs from Canada.

I had an intuitive sense that they would probably agree; 62.7 percent strongly agree, 20.4 percent agree, 83.1 percent of my constituents believe that they should be able to import less costly FDA approved prescription drugs from Canada. Does that statistic surprise you?

Mr. HUBBARD. Not at all.

Ms. SHAYS. The issue is, that's illegal right now?

Mr. HUBBARD. Absolutely.

Ms. SHAYS. Constituents are doing it, correct?

Mr. HUBBARD. Absolutely.

Mr. SHAYS. I'm told the drug companies have basically exported to Canada or allowed to come into Canada basically seven times what Canada consumes, and it's a growing market. How would you begin to even reign in this illegal activity in Canada? Not that I even know if I want you to, frankly. I'm having to deal with it.

Mr. HUBBARD. We cannot, under current law. The current law was established for FDA to inspect a very large volume of an imported drug, say, millions of pills that Pfizer might bring in from a plant in Ireland. And that process worked very well. But when individuals buy these small 60 or 90 day supplies, and it comes in huge quantities to the mail facilities in this country, neither the Postal Service nor Customs nor the DEA nor FDA can in any rational way look at all those products and make any judgments about whether they're good or not.

Mr. SHAYS. Who's breaking the law? Is Canada breaking the law in exporting them, or are my constituents breaking the law when they buy them?

Mr. HUBBARD. It may be a violation of Canadian law, but that is would be for them to determine. The drugs themselves are clearly illegal. FDA, though, has never taken enforcement action——

Mr. SHAYS. But listen to my question. My question is, who's breaking the law in the United States?

Mr. HUBBARD. On some technical level you could argue that the patient is breaking the law by buying those drugs, but the FDA has never attempted to punish a patient for buying drugs.

Mr. SHAYS. So the reality is, whatever we do, we still have that issue out there?

Mr. HUBBARD. The implication issue, as the chairman said at the outset, will still be there.

Mr. SHAYS. And we need to bring some census, both here and overseas. But what I'm wrestling with is, I happen to believe that people should be able to import drugs if they're FDA approved. And what I also wonder about is, these aren't drugs necessarily made in the United States then sent to Canada, they're sometimes made elsewhere and sent to Canada, just as they would be sent to the United States.

Tell me the logic of why my constituents shouldn't be allowed to buy the same drug, and if they can buy it overseas for less, why they shouldn't be able to?

Mr. HUBBARD. Because, Mr. Shays, the assumption people make that those drugs are all U.S. made, high quality drugs, just coming back, is wrong in our view.

Mr. SHAYS. Does it matter if it's U.S. made? But they make an assumption that the drugs they buy here are U.S. made, and they are. So I don't get your point.

Mr. HUBBARD. If you buy a drug here, it's been made in an FDA inspected facility under very strict FDA manufacturing controls. These foreign drugs in many cases do not meet those criteria. So that's the problem. The patient can't make a determination whether they're getting that U.S. made drug you describe or the other drug.

Mr. SHAYS. Do we have statistics that tell us that the drugs they're buying from Canada are mostly not FDA approved?

Mr. HUBBARD. Mr. Taylor can describe a process of screening these shipments. He's done two of those recently that found the vast majority of these actual shipments from Canada are not FDA approved drugs.

Mr. SHAYS. OK. So just tell me the statistics. I don't need to know the process.

Mr. TAYLOR. Sir, I'm not sure we have good statistics. We've tried to determine the percentage, as have others. But the bottom line is that we do believe that as demand here increases, or at least our fear is that as demand here in the United States increases, that the Canadian pharmacies that we now see will get their product from sources that are less reputable than the sources——

Mr. SHAYS. But you're not listening to my question. My question is, do you have statistics that say that the vast majority of the drugs, you're saying it, but you're not giving——

Mr. HUBBARD. We have sampling statistics, yes.

Mr. SHAYS. What is the statistic, that 90 percent, 50 percent, 20 percent, 80 percent, what is it?

Mr. HUBBARD. Well, it's certainly over 90——

Mr. SHAYS. No, no, wait, wait——

Mr. TAYLOR. What the blitz showed was that 70 to 90 percent of the products that were being imported were unapproved. We do not have data——

Mr. SHAYS. Unapproved means not FDA approved?

Mr. TAYLOR. Correct. But we do not have data that tells us how much of the product is manufactured in Canada versus manufactured in England versus manufactured in Asia.

Mr. SHAYS. Let me just finish this by just making a comment. I know my light is on. This is hugely important, that people buy drugs actually need the drugs they buy and have been shown by a medical professional to need them. My only point is that we're saying this isn't illegal, this is illegal from the United States, but we're not enforcing it. And you have ambivalence in Congress on this law. This is a huge, gigantic issue that's just only going to get bigger.

With all due respect to your work, we don't have statistics. We're making claims that we can't back up with statistics.

Mr. TAYLOR. May I respond, sir?

Mr. SHAYS. Sure.

Mr. TAYLOR. We do not have statistics, but we certainly have tangible information. For example, your first question relating to what you should tell your constituents or why your constituents should be concerned about purchasing products over the Internet, 3 weeks ago, and I know this isn't about the——

Mr. SHAYS. Can I tell you this? I don't want to keep—my red light is on. But your bottom line is you don't have statistics right now. If I have a second round I would be happy to get more information.

Chairman TOM DAVIS. Let me just note again, I mean, this is an important issue. But the bill really tackles domestic Internet pharmacies. We don't really go after the other.

Mr. TAYLOR. That's right. My point was that someone purchased contraceptive patches over an Internet site that she thought was a U.S. Internet site. In actuality, she received contraceptive patches that had no active ingredient in them. By the time we completed—and we're not done with our criminal investigation yet—but by the time we completed that investigation, sir, the origin of those patches turned out to be India. We had to actually track through about five or six different sites to determine the origin of the product.

So my only point is that the reason why people need to be concerned is that even though it appears that you're getting an FDA approved product, we do have tangible examples of where people have not received what they wished or hoped that they had purchased. And it was a consumer complaint by this particular consumer that led us to the discovery. What we did is we warned consumers to beware of other products purchased on these sites.

We were not saying that all sites are bad, but we had tangible proof that these were problematic sites and we warned the public that they needed to be careful and talk and consult with their health care practitioner when making a decision whether or not to purchase over some of these sites.

Chairman TOM DAVIS. Thank you.

Let me just ask if any other Members have questions for this panel. Mr. Murphy.

Mr. MURPHY. Thank you, Mr. Chairman. I also compliment you and Mr. Waxman for moving forward on this important legislation. This is rather urgent, because it is such a major issue with regard to abuse and use of the system for doing this.

I want to ask a couple of things. First of all, the physicians who are involved with prescribing these drugs at the other end of the

Web site, in some cases they may not be physicians at all, and in some cases, from other State or other countries, they're not open to any liability at all if they mis-prescribe, if they do not take an accurate history, they're not open to any liability, am I correct in that?

Mr. HUBBARD. The next panel may be better set to answer that question. But certainly we have pointed out that liability concerns must exist here in these cases, because you've got people doing things that are either outside the law or not proper medical practice.

Mr. TAYLOR. And sir, if we can determine that those physicians are a part of a criminal conspiracy, because in some cases, the physicians have an agreement with the Internet pharmacy that's supplying those products, we do include them as part of the defendants in our criminal cases. So they do incur some criminal liability.

Mr. MURPHY. Another question I have with regard to FDA, is there any requirement for pharmaceutical manufacturers to only sell prescription medication to legitimate distributors who will ascribe to some sort of other laws or code of ethics with regard to how those medications will be distributed?

Mr. HUBBARD. Well, in fact, we've been working with the wholesalers and distributors and manufacturers this year to set up standards by which wholesalers will assure, and manufacturers can assure that they are selling to legitimate wholesalers and that the proper questions get asked about where the drug came from. There are some instances in which wholesalers will buy from somewhat fly by night sellers of drugs who offer a deep discount. And that is a way for counterfeit drugs to get into the system.

Mr. MURPHY. There is something I want to bring to the committee's attention, too, another important aspect of this, and that has to do with, even when a physician has face to face contact with a patient, particularly the elderly, there was a recent CDC study, the National Ambulatory Medical Care Survey did a study in which they reported that at least one drug considered inappropriate by experts was prescribed at 7.8 percent of elderly patient visits. That's some 16 million visits a year. This one drug classified as never or rarely appropriate was prescribed nearly 4 percent of the time.

There's a massive amount of medication errors that occur, even when a physician is face to face with an elderly patient. When I look at the charts here of what is available online, particularly some of the anti-depression and pain relief drugs that may have side effects, such as dizziness, etc., nothing is more fearful to an elderly person than falling down, having a hip injury, being hospitalized and having subsequent problems with that.

I cannot possibly imagine a scenario by which someone would be self-prescribing these things in any sort of a way that's actually good for their health. I understand situations in which a patient is seeing a physician and has received a prescription from a physician, a legitimate physician in their area. But I do worry about people self-prescribing, and that is a huge concern. Relatives may say, let's help Mom or let's help Grandma. Here is something that we know helped someone else, let's pursue that.

The consequences can be extremely harmful and deadly. Some 1 in 8 emergency room visits in this country are medication errors; 1 in 12 hospital admissions are related to medication errors. And those are when patients are seeing physicians.

So moving forward on legislation such as this is extremely important. However, under the circumstances where a person is seeing a physician it's helpful. But under the circumstances where someone is still trying to self-prescribe or obtain drugs in unscrupulous manners and use that, I'm very, very worried that there's almost nothing we can do to prevent that. Am I correct?

Mr. HUBBARD. You're absolutely correct, Mr. Murphy. Someone could say on one of these questionnaires, I have hypertension, high blood pressure, when in fact they have hypotension, low blood pressure. And they could order exactly the wrong drug, because the patient is making that decision without the doctor's involvement. Because we don't believe in many cases there is a doctor at the other end, and they certainly don't seem to be asking the right questions of the patient, and they're certainly not meeting and seeing the patient and checking their blood pressure and all that.

So you're absolutely right. This is a problem that needs to be fixed.

Mr. MURPHY. On these, do they know the other medication the patient may be on?

Mr. HUBBARD. It purports to ask some of those questions——

Mr. MURPHY. But they may not know them all, because patients themselves may not know.

Mr. HUBBARD. One of the things we did here, we ordered a drug that is contraindicated to be taken with a different drug called erythromycin. So we said that on the questionnaire, we said, I'm taking erythromycin, and we ordered Lipitor. They sent the Lipitor anyway.

So it appears they didn't even bother to read the questionnaire. It appears in some cases these questionnaires are merely there as a facade anyway.

Mr. TAYLOR. And just to add to that, I think we need to keep in mind there are also different types of questionnaires. There are some questionnaires that are basically all filled in for you, all you have to do is insert your name and your address, and that's it. There are other questionnaires that ostensibly pretend to get all the relevant information, but at the end of the day, as you noted, because there isn't really the proper health care practitioner-patient interaction, you're absolutely right, that there might be critical information that should be gleaned from the patient that is not done. That puts the patient at potential harm.

Mr. MURPHY. My hope is we continue on with these hearings and move forward with this legislation, that Americans will pay attention to the idea that seeing a physician face to face has some room for medication error there alone. Self-prescribing and going to sites that are illegitimate is downright dangerous and deadly, and people have to avoid those sorts of sites, because that is something that is going to end up killing and harming a lot of Americans. Thank you.

Mr. HUBBARD. We agree, Mr. Murphy.

Chairman TOM DAVIS. Thank you. Are there any other members—Mr. Carter, any questions? No other questions. I don't have any others. Mr. Shays, did you want to ask a followup?

Mr. SHAYS. If someone is sent a drug that they didn't have a prescription for and they were to become ill or die, could the pharmaceutical or the Internet organization be found guilty?

Chairman TOM DAVIS. If you can find them.

Mr. HUBBARD. I think you're talking about a tort liability question. We certainly have raised those questions in the case of some businesses that are promoting these. It's not really an FDA question. But one would assume that there would be some liability there.

Mr. SHAYS. I'm struck by the fact that this is so stunning that I didn't know, I mean, not that many of us didn't know, but I'm astounded that I didn't know that you could get something without having some kind of prescription. It tells me frankly that you all have a responsibility as well. The mere fact that I asked you a question about that issue, it would seem to me that FDA needs to be much more proactive.

And they're going to have to, I think, sort out, rather than saying, you know, what's happening in Canada is illegal, but it's still going to continue. I happen to want to make it legal. I don't like people breaking the law, but I want to make it legal in a way that works. But I want to do what the chairman wants to do. And I just appreciate that he's made this an issue that we need to be more aware of.

But I'm saying as well, I think you all have a responsibility to be a lot more proactive on this.

Mr. HUBBARD. Fair enough, sir.

Chairman TOM DAVIS. Thank you. Let me thank this panel very much. We appreciate your questions. Obviously when we get you up here we're going to ask you a lot of things that Members have questions about. But that's not new to you.

Mr. HUBBARD. Thank you, Mr. Chairman.

Chairman TOM DAVIS. We appreciate your insights on the bill. Thank you very much.

We're going to move to our second panel. We have Dr. Jim Thompson, of the Federation of State Medical Boards; Dr. Carmen Catizone, of the National Association of Boards of Pharmacy; Virginia Attorney General Jerry Kilgore; Dr. Rebecca Patchin of the American Medical Association; and representing the National Community Pharmacists Association, Mr. John Rector.

We may have votes, we're going to try to get through everybody's testimony, we may have votes and have to take a brief recess in between. I hope everybody's time can accommodate that. But I will swear everybody in and we'll start the testimony and get as far as we can before we have votes.

Please rise with me and raise your right hands.

[Witnesses sworn.]

Chairman TOM DAVIS. Thank you very much.

Dr. Thompson, we'll start with you and move straight down.

STATEMENTS OF DR. JAMES THOMPSON, M.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES; CARMEN A. CATIZONE, EXECUTIVE DIRECTOR/SECRETARY, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY; JERRY W. KILGORE, ATTORNEY GENERAL, COMMONWEALTH OF VIRGINIA; DR. REBECCA J. PATCHIN, M.D., TRUSTEE, AMERICAN MEDICAL ASSOCIATION; AND JOHN M. RECTOR, SENIOR VICE PRESIDENT OF GOVERNMENTAL AFFAIRS AND GENERAL COUNSEL, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Dr. THOMPSON. Thank you and good morning to members of the committee.

I'm Dr. James Thompson, I'm president and CEO of the Federation of State Medical Boards of the United States. The Federation is a national, non-profit association established in 1912 which serves as a collective voice for its 70 member State medical licensing and disciplinary boards. The Federation's primary mission is to improve the quality, safety and integrity of health care by promoting high standards for physician licensure and practice, as well as supporting and assisting State medical boards and the protection of the public.

As I indicated at the hearing this committee held in March 2003, the Federation has been actively involved as a national leader in the use of telecommunications and the Internet in the practice of medicine for a number of years. In 1996, the Federation published a model act to regulate the practice of medicine across State lines. In 2000, it published guidelines for Internet prescribing. In 2002, it published model guidelines for the appropriate use of the Internet in medical practice, one of the first national standards established for Internet medical practice.

Those guidelines which the Federation recommends be adopted by State medical boards include a key provision, and I'll quote from that provision, a documented patient evaluation, including history and physical evaluation adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment recommended and provided must be obtained prior to providing treatment, including issuing prescriptions electronically or otherwise.

This has been the key interest of the Federation with respect to Internet pharmacies. There must be an appropriate relationship between the patient and the physician before a prescription is written and medication dispensed. In addition to issuing these guidelines, the Federation has aggressively sought to identify Internet pharmacies that are dispensing drugs on the basis of prescriptions written by health care providers whose relationship with the patient does not appear to meet minimal standards.

In September 2000, the Federation of State Medical Boards established the national clearinghouse on Internet prescribing to collect and disseminate information on rogue Internet sites offering prescribing and dispensing services for prescription drugs to consumers. The clearinghouse is uniquely qualified to coordinate information between regulatory and enforcement entities because of its formal relationship with all the State medical boards in the United

States and its territories and its well established lines of communication with State and Federal regulatory agencies, including the Department of Justice, the Drug Enforcement Agency, the Food and Drug Administration and the Federal Trade Commission, as well as the National Association of Boards of Pharmacies, the National Association of Drug Diversion Investigators and the National Association of Attorneys General, representatives of the pharmaceutical industry and the media.

To date, approximately 12 physicians have been the subject of disciplinary action actions based on clearinghouse supplied information. The clearinghouse has supplied information for more than 127 cases at the Federal level and more than 200 cases on the State level. Additionally, information regarding Internet prescribing has been shared with the Medical Counsel of New Zealand and the Ministry of Health in Germany. The Federation strongly supports State based regulation of the practice of medicine.

With regard to Internet prescribing, however, State medical boards have the authority to discipline licensed physicians prescribing and dispensing medications inappropriately. Several boards have already taken action against licensees, adopted rules or policies or introduced legislation to clarify this authority. In addition, State medical boards are communicating among themselves regarding physicians licensed in more than one State. These cooperative efforts have been effective in closing several Internet sites and causing a number of physicians to cease their affiliation with questionable operations.

That said, I also indicated in my testimony last March that there were at least three issues that needed to be addressed through Federal legislation in order to protect patients ordering prescriptions over the Internet. I'm very pleased that H.R. 3880, the Internet Pharmacy Consumer Protection Act, addresses each of those issues.

First, I remarked that patients should know with whom they are dealing. They should know the name and location of the pharmacy that is dispensing the drug, and the name of the physician who will be providing the medical consultation that will be the basis of that prescription. I noted that almost without exception, a State would find that such physician had violated practice standards if he or she wrote a prescription on the basis of an online questionnaire without having any pre-existing relationship with the patient.

Therefore, disclosure will not only be beneficial to patients but will allow State medical boards to identify individuals against whom they can take disciplinary action. H.R. 3880 specifically addresses the issue of disclosure by amending the Food and Drug and Cosmetic Act with the addition of a new section.

Second, I stated that State attorneys general were not able to enjoin operations of an Internet pharmacy that affects citizens in their particular States, if that pharmacy is operated out of another State. Many of our member boards have indicated that they believe that a number of Internet sites that dispense drugs in an appropriate manner could be shut down if the attorneys general had nationwide injunctive powers as well as the ability to pursue other civil remedies, including damages, restitution or other compensation across State lines.

Third, I noted that while State medical boards have the authority to discipline physicians who are prescribing and dispensing drugs over the Internet inappropriately and that many boards had taken such action, State medical boards cannot take action against operators of Internet sites that dispense drugs. I also remarked that while State medical boards believe that the law and regulations governing the physicians in their State are clear as to what constitutes an appropriate physician-patient relationship for purposes of writing a prescription, some courts and prosecutors believed that certain State laws and regulations were ambiguous in this regard. I noted that because of that ambiguity, prosecutors had not pursued certain legal actions.

Last, I offered to work with the committee in trying to craft language that would define an appropriate physician-patient relationship for purposes of regulating Internet pharmacies, while preserving the rights and responsibilities of State medical boards. The language in H.R. 3880, adding a new section to the Food, Drug and Cosmetic Act, strikes a reasonable balance in requiring for the narrow purpose of regulating Internet pharmacies while regulating the exclusive role of State medical boards and defining that relationship under other circumstances.

In conclusion, H.R. 3880 satisfactorily addresses the issues that were raised last year by the Federation of State Medical Boards, and we believe that its enactment into law will provide significant protection for consumers who use the Internet to obtain pharmaceuticals.

I thank you for the opportunity to testify today, and I'll be happy to answer any questions.

[The prepared statement of Dr. Thompson follows:]

Statement of the
Federation of State Medical Boards of the United States
Committee on Government Reform
United States House of Representatives

Presented by James N. Thompson, M.D.
President and CEO

Internet Pharmacy Consumer Protection Act

March 18, 2004

Good morning Mr. Chairman, and members of the Committee. I am Dr. James Thompson, President and CEO of the Federation of State Medical Board of the United States, or FSMB. The Federation is a national non-profit association established in 1912, which serves as a collective voice for 70-member state medical licensing and disciplinary boards. The Federation's primary mission is to improve the quality, safety, and integrity of health care by promoting high standards for physician licensure and practice, as well as supporting and assisting state medical boards in the protection of the public.

Early Interest in Use of Internet for Practice of Medicine

As I indicated at the hearing this Committee held in March 2003, the Federation has been actively involved as a national leader on the use of telecommunications and the Internet in the practice of medicine for a number of years. In 1996, the Federation published *A Model Act to Regulate the Practice of Medicine Across State Lines.* In 2000, it published guidelines for Internet prescribing. In 2002, it published *Model Guidelines for the Appropriate Use of the Internet in Medical Practice*, one of the first national standards established for Internet medical practice.

Those guidelines, which the Federation recommends be adopted by state medical boards, include a key provision:

> "A documented patient evaluation, including history and physical evaluation adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment recommended/provided, must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise."

This has been the key interest of the Federation with respect to Internet pharmacies. There must be an appropriate relationship between the patient and the physician before a prescription is written and dispensed.

Internet Clearinghouse

In addition to issuing these guidelines, the Federation has aggressively sought to identify Internet pharmacies that are dispensing drugs on the basis of prescriptions written by health care providers whose relationship with the patient does not appear to meet minimal standards. In September 2000, the Federation of State Medical Boards established The National Clearinghouse on Internet Prescribing, to collect and disseminate information on "rogue" Internet sites offering prescribing and dispensing services for prescription drugs to consumers.

The Clearinghouse is uniquely qualified to coordinate information between regulatory and enforcement entities because of its formal relationship with all state medical boards in the U.S. and its territories and its well-established lines of communication with state and federal regulatory agencies, including the Department of Justice, the Drug Enforcement Agency, the Food and Drug Administration, and the Federal Trade Commission, as well as the National Association of Boards of Pharmacies, the National Association of Drug Diversion Investigators , and the National Association of Attorney Generals, representatives of the pharmaceutical industry, and the media.

Results of Clearinghouse Activities

To date, approximately twelve physicians have been the subject of disciplinary sanctions based on Clearinghouse supplied information. The Clearinghouse has supplied information for more than 127 cases on the federal level and more than 200 cases on the state level. Additionally, information regarding Internet prescribing has been shared with the Medical Council of New Zealand and the Ministry of Health in Germany.

Enforcing the Law

The Federation strongly supports state-based regulation of the practice of medicine. With regard to Internet prescribing, state medical boards have the authority to discipline licensed physicians prescribing and dispensing medications inappropriately. Several boards have already taken

actions against licensees, adopted rules/policies or introduced legislation to clarify this authority. In addition, state medical boards are communicating among themselves regarding physicians licensed in more than one state. These cooperative efforts have been effective in closing several Internet sites and causing a number of physicians to cease their affiliation with questionable operations.

Need for Federal Legislation

That said, I also indicated in my testimony last March that there were at least three issues that needed to be addressed through federal legislation in order to protect patients ordering prescriptions over the Internet. I am very pleased that H.R. 3880, the Internet Pharmacy Consumer Protection Act, addresses each of those issues.

First, I remarked that patients should know with whom they are dealing. They should know the name and location of the pharmacy that is dispensing the drug and the name of the physician who will be providing a medical consultation that will be the basis of a prescription. I noted that, almost without exception, a state would find that such physician had violated practice standards if he or she wrote a prescription on the basis of an online questionnaire without having any preexisting relationship with the patient. Therefore, disclosure will not only be beneficial to patients, but will allow state medical boards to identify individuals against whom they can take disciplinary action. H.R. 3880 specifically addresses the issue of disclosure by amending the Food Drug and Cosmetic Act with the addition of a new Section 503B(a).

Second, I stated that state attorneys general were not able to enjoin the operations of an Internet pharmacy that affect citizens in their particular states if that pharmacy is operated out of another state. Many of our member boards have indicated that they believe that a number of Internet sites that dispense drugs in an inappropriate manner could be shut down if the attorneys general had nationwide injunctive powers as well as the ability to pursue other civil remedies including damages, restitution or other compensation across state lines. H.R. 3880 addresses this issue by amending the statute mentioned above with the addition of a new Section 503B(c)

Third, I noted that while state medical boards have the authority to discipline physicians who are prescribing and dispensing drugs over the Internet inappropriately, and that many boards had

taken such action, state medical boards cannot take actions against operators of Internet sites that dispense drugs. I also remarked that while state medical boards believe that the law and regulations governing the physicians in their state are clear as to what constitutes an appropriate physician-patient relationship for purposes of writing a prescription, some courts and prosecutors believed that certain state laws and regulations were ambiguous in this regard. I noted that, because of that ambiguity, prosecutors had not pursued certain legal actions.

Last year I offered to work with the Committee in trying to craft language that would define an appropriate physician-patient relationship for purposes of regulating Internet pharmacies, while preserving the rights and responsibilities of state medical boards. The language in H.R. 3880, adding a new Section 503B(b) to the Food, Drug and Cosmetic Act, strikes a reasonable balance in requiring and defining an appropriate physician-patient relationship for the narrow purpose of regulating Internet pharmacies, while recognizing the exclusive role of state medical boards in defining that relationship under other circumstances.

In conclusion, with H.R. 3880 satisfactorily addressing the issues I raised last year, the Federation of State Medical Boards believes that its enactment into law will provide significant protection for consumers who use the Internet to obtain pharmaceuticals.

Thank you for the opportunity to testify today. I will be glad to answer any questions.

Chairman TOM DAVIS. Thank you very much.

Dr. Catizone.

Mr. CATIZONE. Thank you, Mr. Chairman and good morning committee members. Thank you for the opportunity to be here today.

The National Association of Boards of Pharmacy, which I represent, its members are all the licensing jurisdictions in the United States, Canada, Australia, New Zealand, and South Africa. The VIPPS program is an integral component of the services we provide to the States to help them regulate the Internet and protect the public health.

Almost 1 year to the day, we appeared before this committee to report on the activities of the Internet sites offering prescription drugs for sale. Since that time, much has changed and must has remained the same. Domestic, legitimate Internet pharmacies continue to provide valuable and innovative services to their patients.

Although not the focus of the proposed legislation, as Chairman Davis indicated, illegal foreign importation represents a significant threat to State regulation, and is an issue that should be addressed. Rogue or illegal Internet sites distributing prescription drugs without a prescription and based in the United States, although a concern, can be identified, and following appropriate due process, forced to cease operations. The limiting factor for the States is our resources and nationwide injunctive relief.

The required posting of information by Internet sites outlined by H.R. 3880 is an important component of identifying and eliminating rogue and illegal sites. However, NABP is concerned that simply mandating the posting without any credible verification of that information could mislead consumers into believing that illegal or rogue sites are operating legitimately. The required posting will also not address foreign sites which pose the biggest problem for State and Federal regulators.

Some of the examples given today by Mr. Hubbard and others indicate the steps which these rogue or illegal operators will take to confuse the public and hide information. The simple posting of information without verification does not address this critical issue.

NABP applauds the sponsors of H.R. 3880 for addressing the patient-prescriber relationship and supports the language of the bill. The proposed revisions, which identify and define a qualifying medical relationship, will close a regulatory loophole exploited by rogue and illegal Internet sites. Equally as important, the proposed requirement of an in-person medical evaluation will not adversely impact the practices of telemedicine and telepharmacy.

NABP also strongly supports the provisions of H.R. 3880 which allow States to bring civil action forth to enjoin the practices of illegal Internet sites and obtain nationwide injunctions against their operations. NABP's experience indicates that the operators of illegal and rogue sites are extremely knowledgeable about State and Federal laws and will locate their operations to those States or areas where their activities are not specifically prohibited, and may in fact fall within a regulatory grey area. Nationwide injunctive relief will cease these practices and allow States to work together to close regulatory loopholes and eliminate safe havens within the United States for illegal and rogue sites.

NABP and the State Boards of Pharmacy believe that Internet service providers, advertising services and search engines play a direct role in abetting the activities of illegal and rogue Internet sites. The inclusion of advertising on their sites from the rogue and illegal pharmacies misinforms consumers that such sites are legitimate and safe and have been qualified in some way by the ISP, the search engine or the advertising service. Such activity is a matter of concern for the States, and at least one State is preparing a formal complaint against such entities for aiding and abetting in a violation of State and Federal laws.

NABP also requests that the legislation seek to curb the actions of illegal and rogue sites using credit card companies. NABP has been informed that information provided to the House Committee on Energy and Commerce indicates that any purchase made via Web site using a credit card would allow the credit card company to locate the merchant bank and other detailed information on the seller. More importantly, the information presented to the Energy and Commerce Committee notes that the credit card companies could quickly terminate relationships with any vendors of such activities that are illegal.

NABP requests that the provisions of H.R. 3880 which hold harmless interactive computer services or advertising services be reconsidered, and these entities be required to assume responsibility for their acceptance of funding and services from illegal and rogue sites which threaten the public health and safety.

Again, we appreciate the opportunity to share our comments with the committee. We are hopeful that the proposed bill can be revised to address the concerns of the State boards of pharmacy, and we're anxious to work with the sponsors and committee members in achieving this objective of ultimately ensuring that consumers can safely use the Internet to obtain prescription medications.

Thank you.

[The prepared statement of Mr. Catizone follows:]

Testimony of
Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary
National Association of Boards of Pharmacy

Testimony before Committee on Government Reform
United States House of Representatives
Internet Pharmacy Consumer Protection Act

March 18, 2004

Mr. Chairman and Members of the Committee:

I am honored to be here today and discuss with you how to curb the illegal sale of prescription drugs over the Internet, particularly those sales which result without a valid prescription.

The National Association of Boards of Pharmacy (NABP), which I represent, was founded in 1904. Our members are the pharmacy regulatory and licensing jurisdictions in the United States, District of Columbia, Guam, Puerto Rico, and the Virgin Islands, eight provinces of Canada, three Australian States, New Zealand, and South Africa. Our purpose is to serve as the independent, international, and impartial Association that assists states and provinces in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

The Internet and Its Impact on the Practice of Pharmacy

The Internet is a remarkable medium that offers seemingly limitless opportunities for improving how we live and how medications can be dispensed to patients. The legitimate Internet pharmacies serving patients in the US are providing valuable and innovative services to their patients. It is unfortunate that the benefits of these legitimate pharmacies are often overshadowed by the activities of rogue sites whose concerns do not rest with the best interest of the patient or compliance with state and federal laws.

NABP's involvement with the distribution and dispensing of medications from pharmacies utilizing the Internet began in 1997. At that time NABP began to develop the Verified Internet Pharmacy Practice Sites (VIPPS) program, an innovative initiative to inform consumers of legal and safe Internet pharmacies. From the first awarding of a VIPPS certificate in 1999 to the present time, NABP has monitored the activities of Internet sites distributing and dispensing medications. We have observed firsthand the birth, evolution, and revolution of an industry that holds promise for growing populations of patients but, if allowed to proceed along the present course, will remove the Food and Drug Administration's (FDA) drug approval system and the dispensing of medications for chronic diseases out from the US to the country, territory, or back room with the

lowest prescription drug prices, regardless of the standards or safeguards in place in those other countries or territories.

NABP works with the state boards of pharmacy, the FDA and state legislatures to develop regulatory strategies that manage this emerging practice area and provide consumers with the information needed to distinguish legitimate Internet pharmacies from rogue or illegal sites. Our efforts have helped millions of consumers and resulted in the closing of rogue and illegal sites and the prosecution of pharmacists and prescribers involved with those sites. The data we have compiled and collect daily concerning the rogue sites and their operations serves as a useful source of information for other Congressional Committees, federal and state agencies, and consumer outreach programs.

Scope of Internet Sites

In late 1997, NABP and state and federal regulators made the startling observation that Web sites were appearing on the Internet and offering prescription medications to consumers without a valid prescription in direct violation of state and federal laws and regulations. At first, it appeared that such activity was an aberration or the misguided actions of uninformed entrepreneurs who viewed the distribution of medications via the Internet in the same light of opportunity as books and compact discs. However, subsequent research into this emerging area of e-commerce indicated otherwise. NABP detected a clear pattern of lawlessness and disregard for the legal safeguards in place for the practices of pharmacy and medicine.

The numbers of Web sites grew steadily in 1998 and soon were present in all areas of the Web. Data compiled by NABP, the FDA and other state and federal agencies presented a growing area of concern and potential compromise of the US medication distribution system and public health protections. In 1999, a coordinated effort between state agencies (state boards of pharmacy and medicine) and the FDA, and the introduction of NABP's Verified Internet Pharmacy Practice Sites Program (VIPPS) increased consumer awareness about the dangers of rogue or illegal sites, and helped to close a number of rogue and illegal sites. Those efforts were making significant progress in ceasing the operations of the rogue sites when the September 11 attack occurred and provided an unfortunate opportunity for the rogue sites to re-emerge and play on the fears of a shocked nation by offering prescription drugs and products to counter bio-terrorism attacks. The number of sites on the Internet operating outside of the law increased dramatically at this time. Fortunately, the threat of an anthrax attack dissipated in the early months of 2003 and subsequently, the number of sites offering antidotes and prophylactic therapies began to diminish.

In early 2003, NABP again detected a major shift in activity on the Internet. At this time, there appeared to be an unprecedented increase in the number of Internet Web sites offering American consumers lower priced medications from Canada and other foreign sources. Sites involved in this illegal activity jammed the Internet, deluged consumers with advertisements and solicitations at every turn and click, and aggressively lobbied

senior citizen groups and other special interest groups for Congressional support to protect their activities. NABP spoke out at the time, and continues to speak out, against these sites and their illegal activities. NABP has commented extensively on the need to close these sites and end their illegal operations. Working with the states and the FDA, NABP has documented incidences of patient harm from Internet sites and pharmacies operating in Canada and other parts of the world. The illegal distribution of drugs from foreign-based Web sites must be a major concern of any effort to regulate Internet sites. Although not the primary focus of the proposed legislation before the Committee today, such rogue sites must not be ignored.

The VIPPS Program

In early 1999, working with federal and state regulators, consumers, and the legitimate Internet pharmacy industry, NABP developed the Verified Internet Pharmacy Practice Sites (VIPPS) program. The VIPPS program fashioned traditional regulation and consumer empowerment into a thorough and successful verification and authentication system. The VIPPS process developed by NABP encompasses compliance with state and federal laws governing the practice of pharmacy and the direct verification of licensure of the Internet pharmacy with all states where licensure or registration is required. VIPPS certifies, through on-site inspections and the meticulous analysis of the site's operations and submitted written information, compliance with a 19-point criteria review. The VIPPS criteria include verification of valid licensure in all of the US states with additional criteria that concentrate on the distinctions of Internet practice such as the transmission of prescription information and patient data, confidentiality of patient records, and quality improvement and monitoring of prescription processing and patient interactions.

The VIPPS program was implemented with wide consumer acceptance and support. Information about the VIPPS program has appeared on national and local news media programs and consumer information specials. The exposure included programming on CNN, ABC World News Tonight, NPR Radio, NBC News, CBS News, and Fox Special Report. Articles, stories and consumer advice recommending the VIPPS program have also appeared throughout the print media in local newspapers across the country as well as in Time, Newsweek, the Ladies Home Journal, Consumer Reports, USA Today, Wall Street Journal, New York Times, Washington Post, and other national publications. NABP estimates that more than 10 million consumers have heard, watched, or read about the VIPPS program. Government agencies such as the Food and Drug Administration (FDA) and the Center for Medicare and Medicaid Services also reference and recommend that consumers refer to the VIPPS program. Professional organizations such as the Federation of State Medical Boards (FSMB), American Pharmaceutical Association (APhA), and the American Medical Association (AMA) have also referenced and recommended consumers to the VIPPS program to consumers.

In November 2003, NABP and the National Association of Pharmacy Regulatory Authorities (NAPRA) expanded the VIPPS program to include legitimate, legal, and safe pharmacies duly registered in the various provinces. The VIPPS Canada program mirrors NABP's VIPPS program in the US and will identify for Canadian patients legal and safe Internet pharmacies accredited by a credible and valid system with standards that focus on the protection of the public health and patient safety. Presently, those Canadian pharmacies which ship prescription drugs into the US in direct violation of state and federal laws would not qualify for VIPPS certification.

NABP and NAPRA are also in discussions to develop a regulatory framework that regulates the inter-border practice of pharmacy and dispensing of medications to patients in the US and Canada. The framework would provide similar protections as those afforded US patients who utilize pharmacies engaged in the interstate practice of pharmacy and dispensing of medications. The framework will coordinate the regulatory efforts and resources of Canadian provinces and US state boards of pharmacy.

Regulatory Challenges by Practicing Pharmacy Across State Lines

The Internet changed pharmacy practice in a revolutionary manner by allowing for the electronic transmission of prescriptions and patient data, enhanced access to health care information and treatment, improved communications among health care practitioners, and distant care treatment occurring in real time. These advances have also brought new challenges to practitioners and regulators; challenges that question traditional enforcement provisions. For state boards of pharmacy the regulation of US-based sites, although exigent is not impossible. The physical presence of a building (pharmacy or wholesale operation) or person (pharmacist or prescriber) in a state or US territory provides state regulators with the information and access needed to identify these entities and successfully prosecute them. In fact, the combined regulatory actions of states and the FDA have resulted in the disciplining of practitioners, the closing of sites, the restriction of sites from operating in certain states, and multi-million dollar fines.

NABP believes and is on record noting that the state boards of pharmacy and other state regulatory agencies, working with the FDA and other federal agencies, can be effective in monitoring and regulating US-based sites offering prescription medications over the Internet. All states have in place laws and regulations governing the practice of pharmacy. These laws and regulations ensure that the provision of pharmaceuticals and pharmacist care meet accepted standards of practice and protect the public from harm. The various practice acts and regulations also establish the criteria for licensing pharmacists and pharmacies, operating a pharmacy to dispense medications to patients, and disciplining those pharmacists and pharmacies who violate state laws and regulations and endanger the health and safety of the citizens of the states.

The states have determined that Internet sites offering prescription medications are engaged in the practice of pharmacy and therefore must abide by the same laws and rules that presently apply to traditional brick and mortar pharmacies. Internet pharmacies, although unique in their structure and environment, essentially represent the operations of non-resident or mail order pharmacies. The basic construction of these systems involves the receipt of prescription orders from patients who do not physically deliver the prescription orders to the pharmacy and the delivery of prescription medications to patients who reside in locations different than where the pharmacy is located. All activities between these beginning and end points involve the practice of pharmacy and require adherence to present state laws and regulations. Additional regulations enacted in these states to specifically address Internet pharmacies have more specifically identified Internet practice and defined a valid patient-prescriber relationship.

All but a handful of states require that non-resident or out of state pharmacies license or register with them and comply with their applicable laws and statutes. These laws and regulations have been in place for almost 20 years, effectively protecting the citizens of the states and fostering cooperation among the states. What the various laws and regulations governing the practice of pharmacy and Internet sites have restricted is the operation of illegal sites seeking to bypass the regulatory system. State laws and regulations recognize the advantages of the Internet and allow for the practice of telemedicine and telepharmacy. Specific provisions of the majority of state laws and regulations allow for the electronic transmission of prescriptions, shared data bases, electronic patient profiles, and other advantages offered through the Internet and other electronic means. These laws and regulations transfer existing and accepted standards for patient care from traditional activities to the new, non-traditional activities of the Internet.

Review of H.R. 3880

Posting of Practice and Licensure Information

The required posting of information by Internet sites, outlined by H.R. 3880, is an important component of identifying and eliminating rogue and illegal sites from the Internet. NABP is concerned that simply mandating the posting of information, without independent and credible verification of the information, could provide an avenue for rogue site operators to exploit the law and mislead consumers under the guise of complying with the mandated posting requirements. NABP's VIPPS Program provides and validates directly with the appropriate state licensing jurisdiction all of the information H.R. 3880 proposes to require as well as the actual license number in the various states, contact information for the state agency holding the license, indication if the pharmacy has any disciplinary actions against the license, services offered by the Internet pharmacy, and corporate information The VIPPS Program information is identified through the VIPPS Seal and security protected links to NABP's Web site. NABP's VIPPS program also provides consumers with the opportunity to report any problems encountered with the site or the operation of any suspicious site they may have encountered while utilizing the Internet through a consumer awareness and reporting service.

Our experience in determining the true origin of rogue and illegal Web sites indicates that such operations deliberately conceal identifying information or fabricate information to provide the appearance of legitimacy to the site and affiliated persons. It is NABP's position that without this verification and validation of information, rogue sites will post fraudulent information to mislead and confuse the public without any regard for the possible penalties or actions for engaging in such conduct.

Although H.R. 3880 affords the Secretary of Health and Human Services the option of recognizing programs such as the VIPPS to implement the proposed revisions of Section 503B of the Federal Food, Drug, and Cosmetic Act, absent the mandating of a valid and credible certification process, it is highly unlikely that this will occur. Again, if Internet sites are simply required to post information to assist consumers in distinguishing legal Internet sites from rogue and illegal sites without any independent verification of that information, rogue operators will post fraudulent information in complete disregard for the law.

Defining a Bonafide Medical Relationship

NABP applauds the sponsors of H.R. 3880 for addressing one of the most problematic areas of Internet practice, the patient-prescriber relationship. NABP is alarmed by the number of Internet sites that purport to establish a bonafide patient-prescriber relationship through the use of cyberspace consultations or medical questionnaires. In NABP's opinion, the use of a questionnaire or cyberspace consultation as the sole basis for establishing a patient-prescriber relationship does not meet the standards of medical practice and violates state and federal laws defining a bonafide patient-prescriber relationship. The proposed revisions of H.R. 3880 which define a "Qualifying Medical Relationship" will close a regulatory loophole exploited by rogue and illegal Internet sites. Requiring at least one in-person medical evaluation of the patient will help to eliminate the dangerous practices of rogue and illegal Internet sites by establishing a legitimate patient-prescriber relationship. Equally as important, the proposed requirement of an in-person medical evaluation will not adversely impact the practices of telemedicine and telepharmacy. Conversely, the proposed requirement will further qualify the practice parameters of telepharmacy and telemedicine and eliminate those Internet sites which are concerned with exploiting consumers and cannot provide an acceptable medical evaluation because doing so would reduce their profit margin and expose their activities as fraudulent and dangerous.

Nationwide Injunctive Relief

NABP also strongly supports the provisions of H.R. 3880 which allow states to bring civil action forth to enjoin the practices of illegal Internet sites and obtain nationwide injunctions against their operations. NABP's experiences indicate that the operators of illegal and rogue sites are extremely knowledgeable about existing state and federal laws and will relocate their operations to those states or areas where their activities are not specifically prohibited and may in fact fall within a regulatory "gray area." Within this "safety net" the rogue or illegal site will operate in defiance of state and federal law and

without any desire to comply with existing laws and regulations if there appears to be even a scintilla of ambiguity in the law. Nationwide injunctive relief will cease these practices and allow states to work together to close regulatory loopholes and eliminate safe havens within the US for illegal and rogue sites.

Interactive Computer Service Advertising

NABP and state boards of pharmacy believe that Internet Service Providers (ISPs), advertising services, and search engines play a direct and abetting role in the activities of illegal and rogue Internet sites. The inclusion of advertising from these sites on legitimate Internet sites misinforms consumers that such sites are legitimate and safe and have been qualified in some way by the ISP, search engine, or advertising service that accepts and transmits their advertisements or services. States are beginning to take action against such entities for aiding and abetting in the violation of state and federal laws.

NABP requests that the provisions of H.R. 3880, which hold harmless interactive computer services or advertising services be reconsidered, and that these entities be required to assume responsibility for their acceptance of funding and services from illegal and rogue sites which threaten the public health and safety.

Conclusions

NABP appreciates the opportunity to share its comments with the Committee. We are hopeful that the proposed bill can be revised to address the concerns noted by NABP. NABP is anxious to assist the sponsors and supporters of H.R. 3880 in achieving the stated objectives and ultimately in ensuring that consumers can safely use the Internet to obtain prescription medications. Thank you.

Chairman TOM DAVIS. Thank you very much.

General Kilgore, thanks for being with us.

Mr. KILGORE. Good morning. Thank you for inviting me and thank you for the opportunity to testify today on behalf of attorneys general around the Nation.

In the National Association of Attorneys General, I serve as the Chair of the Prescription Drug Abuse Task Force. Many of us have been in Washington this week to discuss important issues facing our States. The issue of prescription drugs being sold over the Internet certainly is one of them.

As we all know, the Internet offers tremendous opportunities for e-commerce, but it's also a wireless trap for fraud and scams, including the health risks involving the online sales of prescription drugs. In July of last year, we posted on our office Web site and issued a media alert warning individuals of the perils of online prescription drugs, including links for information on consumer safety for online prescription purposes.

Thousands of Virginians rely on prescription drugs for their health. Seniors and working families struggle to afford prescription drugs. It is my role as attorney general to ensure that consumers are protected from online fabricated pharmacies whose main concern is the bottom line, not the health of the purchaser. It is necessary to have the law enforcement tools to shut down those rogue pharmacies, and that is why I am here today.

Virginia prides itself on being a business friendly State. As Attorneys General, we often look for creative ways for the public and private sector to work together. There is a legitimate purpose for online prescription sales, but only when it is narrowly tailored to provide the convenience and cost effective purchases following an actual visit with a physician who then prescribes a patient medication that will improve the patient's health. This legislation targets those companies who use privacy concerns and convenience at the expense of the health of the individual.

It is so easy to go to one of these sites and put in information that doesn't accurately portray the health condition, such as a higher weight to allow an individual to purchase diet pills who really doesn't need those diet pills. It is also easy for a child to make up their age to purchase prescription drugs without their parents knowing. It is so easy to go to one of these sites, get a prescription for a self-prescribed condition, something an individual may have read off another Internet site. No questionnaire can replace the diagnosis of a physician who knows the patient and understands their health history.

As attorneys general, we have worked together against rogue pharmacies, but our current enforcement tools are lacking. Right now, enforcement at the State level is limited to the practice of prescribing and dispensing medication through State laws and licensure agreement. Under this legislation, as attorneys general, we need the additional enforcement authority to take these individuals to court to shut down these illegal Internet pharmacies.

It is vital that the Davis-Waxman Internet Pharmacy Consumer Protection Act be adopted to protect our citizens, because we believe the health care of our citizens is being jeopardized. An individual who is savvy with technology can easily startup one of these

businesses and make it difficult for law enforcement authorities to track them down. I want my computer crimes unit to have the authority to go to Federal court and shut down these illegitimate businesses and get nationwide injunctions if necessary.

We need Congress to give us this authority, so that we can continue to protect the health of our citizens. I urge you to act favorably on this important health protection legislation for the constituents of each member of this committee and indeed, all Americans. Thank you so much for allowing me to be with you today.

[The prepared statement of Mr. Kilgore follows:]

COMMONWEALTH of VIRGINIA
Office of the Attorney General
Richmond, VA 23219

Jerry W. Kilgore
Attorney General

REMARKS OF ATTORNEY GENERAL JERRY KILGORE
HOUSE COMMITTEE ON GOVERNMENT REFORM
TESTIMONY ON THE INTERNET PHARMACY CONSUMER ACT
THURSDAY, MARCH 18, 2004
WASHINGTON, D.C.

Good morning. Mr. Chairman, thank you for the opportunity to testify today on behalf of Attorneys General across the nation. Many of us were here this week to discuss important issues facing our states – and the issue of prescription drugs being sold over the Internet certainly is one of them. It is good to be here with my friends from Virginia – Chairman Tom Davis, Congressman Schrock and Congressman JoAnn Davis.

As we all know, the Internet offers tremendous opportunity for e-commerce, but it also is a wireless trap for fraud and scams – including health risks involving the online sale of prescription drugs. In July of last year – we posted on our office web site and issued a media alert warning individuals of the perils of online prescription drugs, including links for information on consumer safety for online prescription purposes.

Thousands of Virginians rely on prescription drugs for their health. Seniors and working families struggle to afford prescription drugs. It is my role as Attorney General to ensure that consumers are protected from online, fabricated pharmacies whose main concern is the bottom line not the health of the purchaser. It is necessary to have the law enforcement tools to shut down these rogue pharmacies and that is why I am here today.

Virginia prides itself on being a business-friendly state. Under my leadership as Attorney General, we often look for creative ways for the public and private sector to work together. There is a legitimate purpose for online prescription sales – but only when narrowly tailored to provide convenience and cost-effective purchases following an actual visit with a physician who then prescribes their patient medication that will improve their health. However, this legislation targets those companies who use privacy concerns and convenience at the expense of the health of the individual.

It is so easy to go to one of these sites and put in information that does not accurately portray your health condition – such as a higher weight to allow an individual to purchase diet pills who doesn't really need them. It is so easy for a child to make up their age to purchase prescription drugs without their parents knowing. It is so easy to go to one of these sites, get a prescription for a self-prescribed condition, something an individual may have read off another internet web site. No questionnaire can replace the diagnosis of a physician who knows the patient and their health history.

As Attorneys General, we have worked together against rogue pharmacies – but our current enforcement tools are lacking. Right now enforcement at the state level is limited to the practice of prescribing and dispensing medications through state laws and licensure agreements. It is vital that the Davis-Waxman Internet Pharmacy Consumer Protection Act be adopted to protect our citizens so that these rogue sites that jeopardize their health and safety are shut down for good.

An individual who is savvy with technology can easily start-up one of these businesses and make it difficult for law enforcement to track them down. I want my Computer Crimes Unit to have the authority to go to federal court and shut down these illegitimate businesses. We need Congress to give us this authority for the protection of the health of our citizens.

I urge you to look favorably on this important, health-protection legislation for the constituents of each member of this committee and indeed all Americans.

Thank you all so very much.

Chairman TOM DAVIS. Mr. Kilgore, thank you very much for being here.

Dr. Patchin.

Dr. PATCHIN. Good morning, Chairman Davis and members of the committee.

My name is Rebecca Patchin, I'm a physician. I practice in Riverside, CA. I'm an anesthesiologist and I practice full time pain management in an outpatient setting.

In June 2003, I was elected to the AMA Board of Trustees and we want to thank you for holding the hearing today on this important policy issue. The safety of Internet prescribing and pharmacies.

The AMA appreciates the opportunity to express our views on Internet pharmacies, and the role of physicians in prescribing and dispensing of medications through these pharmacies. The Internet can be a valuable tool as a medical resource, and we support the use of the Internet as a mechanism to prescribe and dispense medications, as long as appropriate safeguards are in place. These safeguards include ensuring high standards for quality medical care.

I would like to raise three points regarding the regulation of the Internet as a means of obtaining prescription medications. The first is the patient-physician relationship, the second is patient safety regarding the medications they obtain, and the third is the balance of State, Federal and private regulations. First, the AMA believes that Internet pharmacy Web sites or physicians that sell or dispense prescription medications without a prescription or without a valid patient-physician relationship fall well below accepted standards of high quality medical care. They are a threat to the public health.

Any Internet communications between a patient and their physician should supplement and enhance but not replace the patient-physician relationship. The same must be true for Internet transactions between a physician and the pharmacy on behalf of the patient.

For physicians who prescribe via the Internet, a valid patient-physician relationship requires the following. Performing a physical examination of the patient, appropriate to the nature and treatment of the problem that is presenting. Taking a complete and reliable medical history and adequate dialog, followup recordkeeping in order to inform the patients and properly assess the outcome of the therapeutic intervention.

Exceptions to the criteria that I stated above do exist. Those would include covering for a partner on a night or weekend for an existing patient, on call situations and ordering refills for your existing patients. The bottom line is that safeguards must be in place to make sure that patients receive the appropriate medications based on their medical history and physical exams.

Next, with respect to the medications obtained through the Internet, patient safety is paramount. Protections need to be in place to make sure that patients get the medications they need from safe, reliable and identifiable sources, not from fly by night sites that do not meet today's safety standards. The AMA asks that physicians who practice medicine via the Internet disclose identifying informa-

tion on their Web site, including the State or States in which they are licensed.

This type of disclosure requirement should also apply to the Internet pharmacies. In addition, patients need a reliable way to distinguish safe and legitimate sites from fraudulent sites or sites operating below pharmacy standards. To address this problem, the AMA will continue to work with organizations such as the National Association of Boards of Pharmacy to make legitimate sites more easily identifiable.

In addition, the AMA, in conjunction with the State medical societies, will continue to urge our State medical boards to investigate, and when appropriate, to take action against physicians who fail to meet the accepted standards of medical care with regard to Internet prescribing. We also expect that States will continue to explore various methods of regulating the manner and medium in which prescription drugs may be prescribed.

Finally, on the Federal level there are currently several bills, including the chairman's, that address many of the problems we have cited here today in our written and oral testimony. While the AMA has not yet taken a position on any particular piece of legislation, we look forward to working with the Members of Congress to develop appropriate legislative solutions to counter the abusive Internet practices.

Together, we can protect our patients, prevent sub-standard and illegal Internet prescribing and dispensing of medications, and mostly, to ensure that the standards for high quality medical care are fulfilled. Thank you for the opportunity to express our views before this committee. I would be happy to answer any questions.

[The prepared statement of Dr. Patchin follows:]

Statement

of the

American Medical Association

to the

Committee on Government Reform
U.S. House of Representatives

Hearing Entitled: "A Prescription for Safety:
The Need for H.R. 3880 the 'Internet Pharmacy Consumer Protection Act' "

Presented by Rebecca J. Patchin, MD

March 18, 2004

The American Medical Association (AMA) appreciates the opportunity to present our views on Internet prescribing and dispensing of medications to the Committee on Government Reform. We thank the Chairman and Representative Waxman for their leadership on this important issue.

The Internet can be an extremely valuable medical resource, and the AMA supports the use of the Internet as a mechanism to prescribe and dispense medications as long as appropriate safeguards are in place to ensure that the standards for high quality medical care are fulfilled. Web sites that prescribe and dispense prescription medications based solely on an online questionnaire; Internet pharmacies that fail to meet minimum standards for the storage and distribution of prescription medications; and rogue web sites that sell unapproved or even counterfeit drugs are just a few of the grave concerns the AMA has over the current misuse of the Internet for accessing prescription medications.

Another concern of the AMA is the growing availability of controlled substances over the Internet. Today, the nonmedical use of prescription drugs ranks second (behind marijuana) as a category of illicit drug abuse among adults and youth. The National Survey on Drug Use and Health conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA) found that in 2002, an estimated 6.2 million persons in the U.S. over the age of 12 reported "past month" use of prescription stimulants, sedatives, tranquilizers, and analgesics for non-medical purposes. This was a significant increase from 2001 and 2000, when roughly 3.5 million and 1.6 million persons respectively reported such drug use. Additionally, more than 1 in 4 persons aged 18 to 25 report having used prescription drugs for a nonmedical purpose at some time in their lives. A major contributor to the problem has been the ease in which persons can access these drugs over the Internet.

A recent Washington Post article on the "multibillion-dollar shadow market" for prescription drugs stated, "Rogue medical merchants set up Internet pharmacies that serve as pipelines for narcotics, selling to drug abusers and others who never see doctors in person or undergo tests. The sellers move tens of millions of doses of hydrocodone, Xanax, Valium, Ritalin, OxyContin and other controlled substances. Scores of customers have become addicted, overdosed or died." *Washington Post Oct. 19, 2003; p.A01.*

The AMA and a number of national organizations and agencies, including the Federation of State Medical Boards (FSMB), the Food and Drug Administration (FDA) and the National Association of Attorneys General, believe that the prescribing and dispensing of prescription

medications without a valid patient-physician relationship constitutes substandard medical care and is a threat to the public health.

In general, the AMA believes that any Internet communications between a physician and patient, or between a physician and pharmacy on behalf of a patient, should supplement and enhance, but not replace, the critical interpersonal interaction that is the very basis of the patient-physician relationship. The AMA's policy guidance for physicians who prescribe medications via the Internet is clear with respect to the criteria necessary to establish a valid patient-physician relationship, and we believe that serious care should be taken to ensure that these minimum standards of medical care are protected in any effort to regulate Internet prescribing. Our policy (H-120.949) states, a physician shall:

1. Obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided;
2. Have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s);
3. As appropriate, follow up with the patient to assess the therapeutic outcome;
4. Maintain a contemporaneous medical record that is readily available to the patient and, subject to the patient's consent, to his or her other health care professionals; and
5. Include the electronic prescription information as part of the patient medical record.

Exceptions to the above criteria exist in specific instances. These include: instances when treatment is provided in consultation with another physician who has an ongoing professional relationship with the patient and who has agreed to supervise the patient's treatment, including the use of any prescribed medications; and in on-call or cross-coverage situations.

The AMA recognizes that there are a growing number of problems with the use of the Internet for prescribing and dispensing of medications. However, care must be taken to protect and even enhance legitimate electronic prescribing and dispensing practices. The use of the Internet as a source for obtaining prescription medications is not necessarily inappropriate, and a number of appropriately licensed Internet pharmacy practice sites are legitimately dispensing prescription medications pursuant to a valid prescription.

Some examples of the Internet being used for legitimate electronic prescribing purposes are:

- *Computer order entry and on-line transmission of prescriptions.* When a physician sees a patient and does an adequate history and physical, computer order entry and on-line transmission of the prescription to a pharmacy provides an alternative mechanism for prescription transmission. Many experts believe computer order entry of prescriptions can reduce errors that occur from failure to understand handwritten prescriptions. Existing technology allowing for the validation of electronic signatures and the encryption of prescription information can make these transactions even more secure.

- *Ordering refills – either patient to pharmacy, or physician to pharmacy.* There are legitimate clinical circumstances where the physician does not see the patient at the time a refill is ordered, but the patient has been and remains under that physician's care and has been seen in person in the recent past. If the refills are authorized on the original prescription, the patient could electronically contact the pharmacy directly and request the refill. This could be conducted through a community, mail service, or legitimate Internet pharmacy. When no refills are remaining on the original prescription, the patient

could call or electronically contact the physician requesting that a refill be authorized. If the physician believes the refill is needed, the physician could electronically send the renewed prescription to the pharmacy.

- *Electronic consults between physician and patient where the outcome is an ordered prescription.* At times, legitimate clinical circumstances can exist where a physician does not see the patient at the time a new prescription is ordered. This occurs when the patient is under that physician's care, the physician has the patient's history and physical information in the medical record, and the patient has been seen in person in the recent past. For example, a patient may inform his or her physician via telephone or email of a flare up in a seasonal allergy, a documented problem, and the physician may then electronically transmit a prescription for an antihistamine to the pharmacy without an additional office visit. The key here is that the physician and patient have an ongoing relationship, the patient routinely uses this physician, and history and physical information are already in the medical record.

In addition to legitimate electronic prescribing via the Internet, there also are appropriately licensed Internet pharmacy practice web sites that provide an alternative consumer option for the dispensing of prescriptions. Such Internet pharmacies may offer patients a number of benefits including the convenience of ordering their prescriptions from their home or office, as well as the potential to purchase medications at comparative cost savings. However, with the growth and proliferation of Internet pharmacy web sites, it is becoming difficult for patients to distinguish

safe and legitimate sites from fraudulent sites or sites operating below accepted pharmacy standards.

To address this issue, the AMA has worked with and supported the National Association of Boards of Pharmacy (NABP) in its development of the Verified Internet Pharmacy Practice Sites (VIPPS) program. The VIPPS program verifies the licensure of Internet pharmacy practice sites and informs the public, through a database on the NABP web site, whether or not these web sites are licensed in good standing with the appropriate state board(s) of pharmacy or other regulatory agencies. In addition to the VIPPS program, current AMA policy requires physicians who prescribe via the Internet, to clearly disclose physician-identifying information on the web site, including (but not necessarily limited to) name, practice location (address and contact information), and all states in which licensure is held.

Although the AMA supports the VIPPS program, we also recognize that rapid changes inherent in Internet technology may require new efforts or programs to certify Internet pharmacies. Therefore, the AMA stands ready to work with any government or private organization in an effort to develop a program whereby patients will have assurances that an Internet pharmacy, from which they purchase prescription medications, will meet or surpass the standards set for the operation of pharmacies.

For the most part, states have primary jurisdiction over matters relating to medical licensure or the licensing and regulation of pharmacies, both brick and mortar and those operating via mail or over the Internet. Under existing law in the majority of states, prescribing drugs to a patient

outside the state where the physician is licensed is considered the unlicensed practice of medicine. [NOTE: An exception is when the clinical encounter occurs in the state where the physician is licensed.] Every state medical board agrees that prescribing drugs without physically examining a patient or reviewing his or her medical history is, in most cases, practicing medicine at a level far below the accepted standard of medical care. Pursuant to our policy, the AMA has worked and will continue to work with state medical societies in urging state medical boards to ensure high quality medical care by investigating and, when appropriate, taking necessary action against physicians who fail to meet these accepted standards of medical care when issuing prescriptions through Internet web sites that dispense prescription medications. In addition, we expect that states will continue their efforts to regulate prescription-selling web sites while exploring various methods of regulating the manner and medium in which prescription drugs may be prescribed.

In addition to supporting state regulatory activity, the AMA also recognizes that the federal government has a role to play in ensuring the appropriate sale of prescription medications over the Internet by assisting and building on state efforts. The very nature of the Internet makes it virtually impossible for states alone to address the problems surrounding the sale and distribution of prescription drugs between states and between countries. The federal government, especially the FDA, has an especially important role to play with respect to addressing web sites of primarily foreign companies that are illegally promoting, distributing or selling unapproved prescription drug products in the United States. These web sites have multiplied with the growth of the Internet. Typically, these companies will post a price list and advertise that they can sell

United States-patented prescription drug products at greatly reduced prices. In many cases, the advertisements state that the medication can be ordered and obtained without a prescription.

Among the concerns with illegal distribution of drugs from foreign sources is the product quality of these "foreign versions" of prescription drugs and whether patients are at risk of harm due to lack of physician oversight and inadequate directions for use. If obtaining prescription drugs from foreign companies without a prescription through the Internet becomes common, it threatens to potentially render the whole concept of legend (by prescription only) drugs meaningless in the United States. While the FDA has used its authority to prevent this illegal activity by some foreign companies, it has been difficult to stop these and other companies from simply continuing these illegal activities from another web site. The AMA will continue to work with and encourage both federal and state entities to regulate and monitor the Internet sites of companies, whether foreign or domestic, that are illegally promoting and distributing prescription drug products in the United States. The AMA is also hopeful Internet providers, as well as other web sites, will take the initiative to remove links to illegal Internet pharmacy web sites when they are discovered.

The AMA would like to thank Chairman Davis and Representative Waxman, as well as their staff, for allowing us to express our policy positions on H.R. 3880, the "Internet Pharmacy Consumer Protection Act." It is clear that something needs to be done at the federal level to address the myriad of problems surrounding the illegal use of Internet pharmacies.

There are currently several bills that have been introduced or are being prepared for introduction in Congress, including the Chairman's bill, that address the problems of Internet prescribing and distribution. While the AMA has not yet taken a position on any particular piece of legislation, it looks forward to and appreciates the opportunity to work with all Members of Congress in order to craft a solution that will protect patients by preventing substandard or illegal Internet prescribing and dispensing of medications and ensure that the standards for high quality medical care are fulfilled.

Chairman TOM DAVIS. Thank you, Dr. Patchin.

Mr. Rector.

Mr. RECTOR. Good morning, Mr. Chairman and members of the committee. I'm particularly pleased to be here to testify on the Internet Pharmacy Consumer Protection Act, which is directly focused on the domestic marketplace and the Internet traffic in the United States.

The National Community Pharmacists Association was founded in 1898. We represent the professional and proprietary interests of the Nation's community pharmacists, including the owners of 25,000 pharmacies. We are here to enthusiastically endorse H.R. 3880 and commend the Chair and Ranking Member Waxman for the work they have done on this measure.

We especially value the disclosure requirements, the disclosure of the licensure of the pharmacist in the State or States where he or she is licensed. We further strongly support the focus on a bona fide relationship with the physician and echo the testimony of several other witnesses this morning in favor of the injunctive relief for the attorneys general to reach the extra-territorial conduct of these Internet businesses.

I wanted to make just a few additional comments. Whatever is done regarding importation, we think you should focus clearly and in great depth on the domestic marketplace. Basically, Internet is just another form of mail order pharmacy. Also we'd like to take a second to put in context our point of view on these issues.

Only one State has enacted a statute requiring the extra-territorial pharmacies to license a pharmacist in their State. Just one State does that, Arkansas. So it's important to focus on that. So disclosure is a step in the direction of informing the consumer so he or she has the information to know whether or not the pharmacist, if in fact they're dealing with a pharmacist, is someone licensed in their own State. If they had that information, it might help them make the appropriate decision, along with the other criteria, as to whether or not they should be doing business with that particular site.

In our attachment, we highlight a case brought by the U.S. Justice Department versus one of the major domestic mail order companies. We recommend a careful review by the committee members and staff of the allegations there that have extensive implications for the subject of this hearing and related issues.

I note that Florida, California, Illinois, Tennessee, Texas, Michigan, Louisiana, Nevada, Virginia, Massachusetts and D.C. are parties to this whistleblower case that the Justice Department has intervened in, which really highlights the weak infrastructure currently in place regulating domestic mail order.

I listened carefully to the comments of the National Association of Boards of Pharmacy, and we caution the committee not to take any steps in the bill that is eventually reported that would have anti-competitive consequences with regards to various private sector initiatives trying to ferret out the rogue pharmacists and their allies.

And last, we'd like to draw attention also to those that are facilitating these illegal transactions by unlicensed physicians and pharmacies and pharmacists, whether it be the credit card companies

or those that facilitate the shipment to the ultimate consumer in these illegal arrangements. We would encourage the various Federal agencies to address these issues, and frankly, we really don't think the FDA and HHS have aggressively pursued the enforcement of existing statutes. The Justice Department could take a close look at the mail order fraud statutes, RICO and others in trying to address the problem that you have so appropriately highlighted.

Thank you.

[The prepared statement of Mr. Rector follows:]

Statement
of the

National COMMUNITY PHARMACISTS Association

Statement of the
National Community Pharmacists Association
Before
The House Committee on Government Reform

On

The Internet Pharmacy Consumer
Protection Act

10:00 a m – March 18, 2004
2154 Rayburn House Office Building

N C P A
205 Daingerfield Road
Alexandria, Virginia
22314-2885

STATEMENT OF JOHN M. RECTOR

BEFORE THE HOUSE COMMITTEE ON GOVERNMENT REFORM

March 18, 2004

Mr. Chairman, Members of the Committee

I am John M. Rector. I serve as Senior Vice Present of Government Affairs and General Counsel for the National Community Pharmacists Association (NCPA), formerly the National Association of Retail Druggists.

I want to thank you for inviting us to testify on the Internet Pharmacy Consumer Protection Act, H.R.3880.

The National Community Pharmacists Association (NCPA), founded in 1898, represents the professional and proprietary interests of the nation's community pharmacists, including the owners of 25,000 pharmacies. Independent pharmacists serve 18 million persons daily. NCPA has long been acknowledged as the sole advocate for this vital component of the free enterprise system. For decades we have been the only national pharmacy association with universal state association membership, including those of the Committee's members.

Our members function in the market in a variety of forms. They do business as single stores ranging from apothecaries to full line high volume pharmacies; as multiple location entities (e.g. 100 pharmacies) and as franchises such as the 1200 pharmacies involved with the Medicine Shoppes franchise. Whatever the form of business entity, however, independent pharmacists are the decision makers for this wide variety of NCPA member companies.

As owners, managers and employees of independent pharmacies, our members are committed to legislative and regulatory initiatives designed to protect the public and to provide the pharmacist a level playing field and a fair chance to compete. We appreciate the opportunity to assist the Committee in assessing the regulation of Internet pharmacies and pharmacists.

First and foremost we are guided by the premise, universally upheld by the federal courts, that the regulation of the practice of pharmacy by pharmacists and other learned professions rests exclusively with the respective states. This authority includes the registration of a pharmacist to practice pharmacy. In recent years the agencies delegated to exercise the state authority, typically the State Board of Pharmacy, appointed by the Governor, have struggled to provide consumers' equitable protection when pharmacy is practiced interstate via the US mail or by private mail order companies.

NCPA sees Internet pharmacy as a possible vehicle for good patient education and care if the proper safeguards are in place. However, if controls are not in place or not enforced these enterprises create serious problems. Consequently, the Internet pharmacies raise major issues and concerns for those trying to assure the quality and care that patients have a right to expect.

In our view the core concept that must be kept in mind is that Internet pharmacy is unregulated mail order pharmacy. While the ordering process may be different from the typical mail order scheme, the professional, regulatory, and shipping aspects are the same. Therefore, NCPA's long-standing position on unregulated mail order is relevant. NCPA's March 2004 Statement of Positions states:

> **Internet Pharmacies**
> NCPA encourages the equitable application of existing authority to level the playing field with regard to regulating interstate, Internet, and mail order pharmacy as they relate to patient safety and care. NCPA reaffirms its position that the states already have the *sole* authority to license and register pharmacies and pharmacists who practice pharmacy in the consumer's state.
>
> **Unregulated Mail Order Drug Programs**
> Mail order drug programs represent a serious threat to public health. It is not possible for mail order drug vendors, which lack face-to-face contact with patients, to comprehensively monitor their patients' health status, gather information on the full spectrum of their prescription and nonprescription drug use patterns, or adequately assess their understanding and compliance with drug therapy.
>
> NCPA questions the integrity of a drug distribution system that relies exclusively on the mails and in which drugs are dispensed in excessive volume, over long distances, often exposed to extreme temperatures or humidity, delayed, and otherwise compromised. NCPA supports legislative and regulatory actions that apply professional and consumer protection standards to mail order vendors, and urges appropriate officials to investigate the practice and subject mail order drug vendors to appropriate state and federal consumer protection laws, including state pharmacy practice acts.

> NCPA urges the National Association of Boards of Pharmacy and its member state boards of pharmacy to adopt parallel equitable protection for patients who are presently exposed to mail order pharmacists and pharmacies unregulated in their states.
>
> The association further supports the elimination of any federal prescription drug coverage favoring mail order pharmacy, and asserts that the government should require companies providing drugs to federal employees to abide by the laws of the states of the beneficiaries receiving the drugs. In addition, the association supports the enactment of legislation and appropriate regulations designating all prescription drugs as poisons or dangerous substances, thus prohibiting the mailing of such substances, via either the postal service or private carriers, to consumers, as is currently the case with other dangerous substances.
>
> NCPA has developed model legislation for states to use in their efforts to regulate out-of-state mail order pharmacies and pharmacists.
> The integrity of the current drug distribution system is being undermined by foreign, unregulated mail order pharmacies and pharmacists; by the acquisition and distribution of prescription drugs without a prescription via the Internet and U.S. Postal Service; and by the gross abuse of "personal use" exemptions for prescription drugs at our borders. Therefore, the White House should develop a comprehensive, coordinated multi-agency action plan to protect the health and safety of Americans, and to prevent further erosion of the U.S. prescription drug distribution system, including the prosecution of those operating unregulated mail order companies, those selling prescription drugs without a prescription on the Internet, and those abusing personal use exemptions as a guise to import unapproved and misbranded prescription drugs.

It is noteworthy that "pharmacies" do not practice pharmacy and it is the conduct of pharmacists who elect to dispense in a resident patient's state that must be addressed.

Another way of approaching this issue is to ask: "Why should the resident pharmacist abide by the laws and regulations of the resident patient's state if the non-resident pharmacist, in competition with them, is permitted to violate such laws and regulations, including practicing without a resident state's pharmacist license?"

The advent of mail order pharmacy marketed via the Internet has only served to further challenge state efforts to equitably protect consumers. There are opportunities to help control illegal interstate activities by Internet pharmacies and pharmacists while fully respecting the exclusive authority of the states to regulate the practice of pharmacy.

NCPA enthusiastically endorses H.R.3880. Requiring the internet pharmacy website to display information regarding the business, the physicians and the pharmacists associated with it, as well as the licensure of physicians and pharmacists could enhance collaboration between federal and state authorities. Further, such disclosure would assist inquiring consumers in making a better informed decision about whether or not to utilize the internet pharmacy.

Requiring a patient to actually be examined by the prescribing physician is essential to assuring the appropriate care for the patient and will facilitate compliance with the patient's state laws regulating physicians who prescribe and pharmacists who dispense prescription drugs to the patient.

Providing the states with new enforcement authority similar to the Federal Telemarketing Sales Act, permitting state Attorneys General access to federal injunctive relief to enforce state laws regulating the licensure of resident and non-resident pharmacies and pharmacists, will in our view especially assist efforts to curb the illegitimate online conduct of pharmacies and pharmacists.

Generally we are not satisfied with the state and federal monitoring and law enforcement regarding mail order pharmacies. Although recently the volume of illegal Canadian drug mail order imports has received special isolated attention from such authorities, it is estimated that Americans buy that amount of prescription drugs from domestic mail order businesses, including that facilitated by the internet, every two weeks. (See Attachment A - FDA Drug Scrutiny Rapped as Uneven, *Boston Globe* September 16, 2003 article. See Attachment B – US Justice Department's release regarding intervention in major pharmacy benefit manager (PBM) mail order scandal case and also see Attachment C - resolution on U.S. mail order prescription drugs was unanimously approved by the NCPA's House of Delegates at our 105th Annual Convention in Seattle, Washington, on October 22, 2003).

Also, we support the priority application of current laws (e.g. RICO and the Prescription Drug Marketing Act) by the Treasury, Health & Human Services, Justice Departments and other agencies, and the vigorous investigation and appropriate prosecution of the so called "rogue" Internet pharmacies, whether they are doing business in the US or through "offshore" mail order imports.

Whatever additional steps are adopted it is essential that patient care provided by properly licensed pharmacies and pharmacists, engaged in lawful conduct, not be the targets of investigations or regulations.

In conclusion, the legislation, H.R.3880, will help deter unlawful use of the Internet and consequently consumers are far more likely to receive lawfully prescribed prescription drugs and related pharmacists services from legitimate, properly licensed pharmacies and trustworthy appropriately licensed pharmacists.

We look forward to assisting the Committee as it addresses the regulations of Internet pharmacies and pharmacists.

boston.com

(Attachment

THIS STORY HAS BEEN FORMATTED FOR EASY PRINTING

The Boston Globe

FDA DRUG SCRUTINY RAPPED AS UNEVEN

Author(s): Christopher Rowland, Globe Staff **Date:** September 16, 2003 **Page:** A1 **Section:** National/Foreign

The Food and Drug Administration is serious about monitoring the safety of **mail-order** drug shipments in the United States - if they come from Canada.

Last month, the agency conducted an unusual sting operation targeting the City of Springfield, which is importing lower-priced drugs from Canada for city workers to reduce the spiraling cost of drugs bought in the United States. In an elaborate undercover operation, the FDA received at room temperature a single order of insulin that should have been chilled. The agency publicized the sting nationally to illustrate what it described as the dangers of ordering drugs by Internet from Canada. But the FDA takes a hands-off approach to enforcing the much greater volume of prescription shipments from US Internet **mail-order pharmacies**, where increasing numbers of Americans get their drugs. In fact, FDA officials said they can't recall ever conducting a domestic sting operation targeting the quality of insulin or other drug shipments.

Critics said the agency is in the pocket of US drug makers, which have vigorously tried to shut down Canadian imports.

"I'm very concerned that they are selectively enforcing here," said Springfield Mayor Michael Albano, who is heading to Washington for meetings today with FDA officials to make his case. "They're doing the pharmaceutical companies' bidding to try and stop the momentum."

Though rising, Canadian drug imports totaled just $700 million last year. In comparison, Americans buy that amount of drugs every 10 days from domestic **mail-order** prescription businesses, and the level is growing fast.

Meanwhile, there are concerns that the lack of FDA oversight of US shipments is a problem. According to a study using dummy packages with temperature sensors sent to 32 states, one in four **mail-order** prescription deliveries in the United States is likely to be exposed to excessive heat while en route to the consumer. In some cases, especially with biologic drugs, excessive heat can diminish the drugs' effectiveness.

The study was conducted by US Pharmacopeia, a Rockville, Md., nonprofit group that sets national standards for **pharmacies**. The group has encountered industry resistance to spending on new technology to ensure safer deliveries.

"I have never, ever had insulin arrive cool in 13 years of buying it" through domestic **mail order**, said diabetes patient Tom Boyer of San Francisco. He throws the lukewarm cold packs that arrive with his 90-day insulin supplies into the freezer. When they get cold again, he uses them to soothe a sore knee.

US Representative Bernard Sanders, Independent of Vermont, who advocates legislation to allow the importation of low-cost Canadian drugs, said the Springfield sting and lack of US enforcement are evidence that the FDA is helping drug companies protect higher drug prices paid by American consumers.

"The FDA is working for the pharmaceutical industry, which contributes huge amounts of money to the Republican Party and the president," Sanders said.

The FDA declined to respond specifically to charges that the agency favors industry.

"Our policy is based on promoting the safety of the American people," said Brad Stone, an agency spokesman in Washington. William Hubbard, the FDA's associate commissioner for policy and planning, said the Springfield sting was necessary because there are no other mechanisms to hold Canadian companies accountable.

Hubbard said the FDA "absolutely" has the jurisdiction to regulate the safety of domestic **mail-order** shipments. But he said enforcement at the state level ensures that consumers are protected.

"No American pharmacist is going to give you hot insulin," he said. "He's going to be subject to licensure, subject to inspection, subject to a complaint from a patient. His business is going to be at risk. This guy in Canada has nothing at risk."

The Springfield municipal program has been a focus of the FDA since Albano unveiled it in July. Importing prescription drugs from Canada is illegal, yet the FDA has declined to enforce the prohibition for individual consumers. The purchases have increased over the last four years as Americans desperate to reduce their medicine costs have found discounts as low as 50 to 80 percent on brand-name drugs north of the border, a result of Canadian government price controls. The US House has passed a bill that would make Canadian sales in the United States legal. The proposal is hotly opposed by the FDA and industry, which say American consumers could be exposed to counterfeit, expired, or improperly stored medicine from Canada.

It was against this backdrop that the FDA, using an assumed name and address, took action last month against Springfield's supplier of Canadian drugs, CanaRx Services Inc., based in Windsor, Ontario. The FDA said the sting resulted in a room-temperature batch of insulin that should have been delivered refrigerated. Hubbard said the package was not insulated but declined to release other details.

In the United States, some diabetics say insulin ordered from domestic **mail-order** companies often shows up at their doorstep at room temperature.

Concord author Philip Luber said he tried **mail-order** insulin for his daughter in 1999. The insulin that arrived via Federal Express, he said, was not refrigerated and arrived lukewarm. After his daughter began injecting the new batch, her glucose levels did not fall sufficiently, evidence, he believes, that the insulin had been degraded by extreme heat during shipment. Luber persuaded his insurance company to allow him to purchase the insulin at a local drugstore instead.

"The packages they were using were called insulated packages. It had layers of something in it, bubble-wrap or other insulation," he said. "But if you stick any kind of package in a hot truck for a couple of days in the middle of August, it doesn't matter."

For at least the past five years, US drug companies, wholesalers, and **mail-order pharmacies** have joined forces to oppose a set of proposed national prescription-shipping standards that would include the use of temperature sensors in packaging to tell consumers if their **mail-order** prescriptions had been exposed to extreme heat or cold. Without such sensors, proponents say, patients have no way of knowing if the drugs arriving on their doorstep were baked in a truck in the Arizona desert or frozen solid in the belly of a cargo plane.

"The concern has always been that when a **mail-order pharmacy** ships, it's being sent to the consumer under uncontrolled conditions," said Eric C. Sheinin, vice president for standards development at US Pharmacopeia, the standard-setting group.

US **mail-order** companies are generally regulated by individual state boards of **pharmacy** following US Pharmacopeia guidelines.

The FDA's Hubbard said the agency's rules establish US Pharmacopeia as the standard-setting entity for the operation of **pharmacies**, including national-scale **pharmacies** that ship across state lines. But US Pharmacopeia said it has no shipping standards, which has been a source of concern among some US Pharmacopeia officials. A 1997 study by the organization, in which test packages were shipped to 32 states, demonstrated that 26.1 percent of **mail-order** drugs were exposed to excessive heat of 104 degrees or more, well above the tolerance for insulin, for example. A 1995 study found that temperatures in St. Louis mailboxes reached 136 degrees.

Manufacturing guidelines for insulin say it should be stored in a refrigerator, although it can be kept safely at room temperature for up to 28 days. It loses effectiveness when it is exposed to greater than body temperature. The problem for **mail-order** consumers is that there is no way to tell by looking at the product if it has been heated beyond tolerable levels. Freezing insulin renders it almost completely ineffective, but there are telltale signs of freezing, such as a cloudy appearance.

The National Community Pharmacists Association has called on the federal government for greater regulation of Internet **mail-order pharmacies**, to no avail, said John M. Rector, the association's general counsel.

US Pharmacopeia has repeatedly proposed national guidelines to safeguard drugs in shipment, including the insertion of temperature sensors into packages of sensitive prescriptions like insulin and synthetic hormones. Those proposals have been defeated by "push-back from industry," which holds seats on the US Pharmacopeia governing bodies, Sheinin said. The organization's leadership plans to unveil a fresh set of proposals within two weeks.

The FDA's director of **pharmacy** affairs, Tom J. McGinnis, said the FDA would enforce whatever standard US Pharmacopeia adopts. Thus far, he said, the agency has not seen the need for independent action.

"FDA looked at this issue in the past, at least 10 years ago, when **mail-order pharmacies** started getting big," he said, "and

we didn't see any degradation of strength, quality, and purity at that time."

The Pharmaceutical Care Management Association, which represents **mail-order pharmacies**, and the largest **mail-order pharmacy**, Medco Health Solutions Inc., declined to comment on US Pharmacopeia's proposals for temperature sensors. In the past, according to copies of industry newsletters, **mail-order pharmacies**, wholesalers, and drug manufacturers have said that requiring sensors would present an unfair regulatory burden, raise handling costs, and increase the likelihood that consumers would return drugs to **mail-order** retailers.

"**Mail-order pharmacy** sources are already appropriately regulated by state boards of **pharmacy**," said Tim Brogan, a spokesman for the Pharmaceutical Care Management Association.

Medco Health Solutions, a subsidiary of drug maker Merck & Co., said **mail-order** pharmacists take great pains to make sure drugs arrive in good shape. Medco spokeswoman Ann Smith cited several measures including overnight or expedited shipping, iced or gel-packed insulated containers, and follow-up calls to an insured patient to see if the package arrived on time.

"We believe that our protocols are extremely rigorous," she said.

Christopher Rowland can be reached at crowland@globe.com.

Perform a new search

Press Release

(Attachment B)

UNITED STATES ATTORNEY'S OFFICE
NEWS RELEASE

U.S. FILES COMPLAINT IN INTERVENTION IN TWO "WHISTLEBLOWER" ACTIONS AGAINST MEDCO HEALTH SOLUTIONS

Alleged Violations Include Cancelling, Deleting, or Destroying Patient Prescriptions To Meet Contract Turnaround Requirements, Creating False Records about Calls to Physicians, Shorting Prescription Orders, Making False Statements to Patients, And Switching Patients To New Drugs Without Physician Authorization

September 29, 2003 - PHILADELPHIA - United States Attorney Patrick L. Meehan announced today the filing of the Government's complaint in intervention in two "whistleblower" actions brought under the federal False Claims Act and state False Claims Acts against **Medco Health Solutions, Inc. ("Medco")**. This action follows the notice of intervention filed in the pending actions on June 23, 2003.

In these actions, USA ex rel. Hunt and Gauger v. Medco and USA ex rel. Piacentile v. Medco, the "whistleblowers" or "relators" alleged that Medco submitted and caused the submission of false claims to the United States, that Medco made false statements and prepared false records in support of false claims, and that Medco made false statements to reduce its liability for penalties to the United States. These violations, according to the complaints, arose out of Medco's contract with the Blue Cross and Blue Shield Association to provide mail order prescription drug benefits to federal employees, retirees, and their families.

"The conduct alleged in the complaint is a financial fraud on employee health benefits programs funded in whole or in part by the United States. Moreover, it is a fraud on the patients who rely upon Medco mail order pharmacies for their prescriptions, and on the judgment and professionalism of the licensed pharmacist which safeguards their health," said Meehan. "Patients who use mail order pharmacies have paid for and should receive the same professional quality and commitment that they receive from their neighborhood pharmacist. Pressure by an employer to reduce costs and increase profits must never be allowed to coerce pharmacists into ignoring their duties to patients. Getting the proper medication in the hands of patients as quickly and efficiently as possible should be the mission of any pharmacy benefit manager. However, these allegations suggest that, somewhere along the line, the focus became the profit instead of the patient."

The Complaint filed today alleges that Medco engaged in the following conduct:

1) Cancelling, deleting and destroying patients' mail order prescriptions so that Medco could avoid penalties for its repeated delays in filling and mailing patient prescriptions;

2) Mailing prescriptions to patients with less than the number of pills ordered and paid for ("shorting"), and charging both patients and health plans as if they had dispensed the full amount;

3) Creating false records showing that physicians had been contacted to discuss the proper drug, or the proper dosage or dispensing instructions, when no such contact had been made;

4) Creating false records showing that physicians had been contacted to discuss the risk of adverse drug interactions for a patient, when no such contact had been made;

5) Intimidating and coercing pharmacists in order to certify new prescriptions for filling without direct contact with the treating physician, when the professional judgment of the pharmacist was that a call was required;

6) Making false statements to patients that mail order prescriptions had not been received, when in fact the prescription had been received and then cancelled in order to appear to meet contractually required turnaround times;

7) Billing the United States and patients for prescriptions not authorized by law to be filled;

8) Making false statements to the United States during the investigation of Medco's illegal conduct;

9) Changing prescriptions based upon misleading or false information provided to treating physicians;

10) Making false statements to the Blue Cross Blue Shield Association about compliance with contract requirements that prescriptions be mailed within so many days of receipt;

11) Inducing physicians to authorize switching of prescriptions from lower to higher cost medications while representing that the switch was for the purpose of reducing prescription costs for the health program;

12) Favoring Merck drugs over other manufacturer's drugs in switching programs, even when the Merck drugs were more expensive;

13) Failing to comply with state laws requiring appropriate drug utilization review by a pharmacist and consultation with the treating physician where there is a potential for harmful interaction among drugs prescribed for a patient;

14) Fabricating records of calls by pharmacists to physicians;

15) Failing to call physicians for clarification, as required by governing law, when the prescription received by the pharmacist is ambiguous.

The Government's Notice of Intervention was limited to Count 1 of the Hunt/Gauger complaint, and Counts 1 and 2 of the Placentile complaint. The decision by the Department of Justice to intervene in a case does not necessarily mean that it endorses, adopts, or agrees with every factual allegation or legal conclusion in the relators' complaint. Copies of the Government's Complaint in Intervention, the Government's notice of intervention, and each relator's complaint are available on the U.S. Attorney Web site, www.usdoj.gov/usao/pae.

Under the False Claims Act, a "whistleblower," known as a "relator," files a complaint on behalf of the United States "under seal," that is, with the District Court in files not available to the defendant or the public. After investigation, the United States must decide whether to intervene and participate in the prosecution of the action with the relators' counsel, or to decline to participate

and permit the relators' counsel to prosecute the action alone. The relator retains the right to prosecute declined claims or parties. The case is unsealed by the court at the time of the intervention or declination.

It is customary for the United States, upon intervention in a pending qui tam action, to prepare, file and serve its own complaint after the date of intervention. This amended complaint sets forth the factual allegations that the United States is prepared to adopt and allege against the defendants as the result of its investigation. In whistleblower actions in which the United States intervenes, the United States may adopt some or all of the relators' factual allegations. The United States' complaint may assert additional claims under statutes other than the False Claims Act, or the common law which the relators are not entitled to assert. The United States may also assert claims under the False Claims Act or other laws against individuals or entities not named in the relators' complaints.

These qui tam actions, both filed in the United States District Court for the Eastern District of Pennsylvania, have been consolidated and assigned to Senior Judge Clarence Newcomer.
In this case, as in all civil False Claims cases, the claims made in the complaints are allegations only. The defendants have a right to a jury trial on each of the claims, and the United States must prove each of the claims by a preponderance of the evidence. Each of the defendants has the right to present evidence on its behalf, and to cross-examine witnesses called by the United States and the relators.

The notice of intervention follows an extensive investigation of the factual allegations and evidentiary support provided by the relators. This investigation was conducted by the United States Attorney's Office, Eastern District of Pennsylvania, together with the Office of Inspector General of the Office of Personnel Management, The Office of Inspector General of the Department of Health and Human Services, and the Defense Criminal Investigative Service. State Attorneys General are also examining related issues in coordination with the Department of Justice.

The handling of this case by the United States Attorney's Office is primarily assigned to James G. Sheehan , Associate United States Attorney.

UNITED STATES ATTORNEY'S OFFICE
EASTERN DISTRICT, PENNSYLVANIA
Suite 1250, 615 Chestnut Street
Philadelphia, PA 19106

Contact:
RICH MANIERI
Media Contact
215.861.8525

(Attachment C)

RESOLUTION #4

U.S. Mail Order Prescription Drugs

WHEREAS, the national debate about illegal prescription imports has highlighted the lack of appropriate regulation of U.S. domestic mailers of prescription drugs and of the pharmacists and non-pharmacists responsible for such mailings; and

WHEREAS, the U.S. Food and Drug Administration and others have recently acknowledged the lack of monitoring investigation of U.S. mail order drugs, which surpasses the volume of illegal Canadian prescriptions every 10 days; and

WHEREAS, the pharmacy benefit managers disingenuously claim both that they do not practice pharmacy and that their pharmacists are the only pharmacists that provide worthwhile services; and

WHEREAS, the U.S. government in United States of America vs. Medco (9/29/03) claims that the poster child of unregulated U.S. mail order prescriptions and mail order pharmacists has engaged in systematic abuse of consumers, especially federal employees, including military personnel and their families;

BE IT RESOLVED THAT NCPA revise its model mail order state regulation bill and request appropriate state authorities to enforce current law and enact appropriate new laws, if necessary, to ensure that patients exposed to mail order prescriptions have the benefit of the relief and remedies available to non-mail order consumers of prescription drugs.

Chairman TOM DAVIS. Thank you very much.

Dr. Thompson, I understand you need to leave at 12:00?

Dr. THOMPSON. I'll stay as long as you need me.

Chairman TOM DAVIS. We will not have an intervening vote, so that's good. Let's start the questions, I'll start with you, Dr. Thompson. H.R. 3880 gives State attorneys general Federal injunctive relief against online pharmacies that are in violation of the law. What impact do you think this injunctive relief will have on shutting down the rogue Internet pharmacy Web sites?

Dr. THOMPSON. The principal problem that we've encountered, quite frankly, is the hesitancy of a number of attorneys general and the inability of them to go after these rogue sites. That's only superseded by the fact that it's very difficult to locate where they are. Their location and change of location is as simple as changing a Web page on a daily basis.

But it would significantly increase an attorney general's ability to close down pharmacies that are operating in not only other States, but multiple States, and be able to go after those rogue sites as well as allowing us to go after the physicians that are involved in this practice.

Chairman TOM DAVIS. Mr. Kilgore, do you agree with that?

Mr. KILGORE. I do, Mr. Chairman. It's important that State attorneys general have this ability. How I envision it would work is that we would join together with other attorneys general around the Nation when we identify one of these sites to go in and shut it down.

Chairman TOM DAVIS. You still have a problem identifying it, but at least now you would have a legal recourse, which you really don't now.

Mr. KILGORE. That's right. It's much the way we have to do, Mr. Chairman, with spammers under Virginia's anti-spam law, under the new one passed by Congress. It's difficult to identify these individuals because criminals find new ways every day to go out and make money. But we can do it just, the authority, the injunctive authority gives us greater abilities to go into Federal courts and shut them down.

Chairman TOM DAVIS. What we continue to see is consumers going to these Web sites, though. What's troubling is that consumers are going to the Web sites because they think they're getting cheaper drugs or whatever. And we today have heard a lot of testimony on how bogus a lot of these drugs are. Aside from the fact that even if they were correct, they may or may not work and do what they were prescribed to do, because you don't have the physician-patient relationship, many of these drugs are actually bogus. We passed some around up here that are routinely delivered over the Internet.

What do we do to better inform consumers of the problems in this?

Mr. CATIZONE. Mr. Chairman, I think that's a major dilemma, because we're sending mixed messages to consumers. On one hand we're telling them it's OK to import medications from Canada, and we don't know if those sources are truly Canada, and on the other hand, we're saying they're very dangerous, and we have examples of those dangers, counterfeit drugs. We've received over 100 con-

sumer complaints about medications ordered over the Internet, at least $20,000 worth of consumer fraud where they ordered medications and didn't receive those medications, and a number of complaints that the products were counterfeit or didn't have any active ingredient whatsoever.

So that's a significant challenge for us, sending one message to the consumer about using the distribution system that's approved and safeguarded by the FDA and State agencies.

Chairman TOM DAVIS. I guess if anybody, if they would counterfeit a prescription, with a physician writing a prescription, without it, they'd certainly counterfeit the drug, I don't know why there would be any difference on that. Does anybody else have any observations on that?

Mr. KILGORE. Mr. Chairman, I would say that traveling around Virginia and speaking with senior organizations, I've picked up on the mixed messages that they are getting as well. That's why we felt it was important to weave into every presentation to senior organizations around Virginia the fact that you must be sure who you are dealing with when you are ordering prescriptions online or, and reminding our seniors that Virginia law does not allow the importation, and further making it clear that you need to retain that doctor-patient relationship, so that they know exactly how each drug interacts with other drugs.

Chairman TOM DAVIS. Dr. Patchin, let me ask you, you didn't specifically endorse any piece of legislation. I know your organization is careful not to do that. But do you think the provisions that we have in this legislation that Mr. Waxman and I have drafted, defining an appropriate medical relationship is consistent with AMA guidelines regarding prescribing medications?

Dr. PATCHIN. Yes, they appear consistent. And on your last question, I might add, I practice in a border State, and a State where the importation is not Canada, and where many of our imported medications come in. I view it as patient education, something that I work with one on one with my patients about the safety of the medications that they may get from other areas by driving a few hundred miles. Again, they need to look at safety and whether the medication is really what they're getting.

Chairman TOM DAVIS. My time is up, but real quick, does the AMA think it's important for Internet pharmacy sites to disclose physician identifying information, like their licensure information on their Web sites?

Dr. PATCHIN. Yes. In my testimony, I stated that the physician and the pharmacy should have identifying information, so that the patient could contact the pharmacy as well as the physician.

Chairman TOM DAVIS. Thank you very much. Mr. Waxman.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

Mr. Kilgore, you testified about the importance of the provision in this bill that would give State attorneys general the ability to shut down illegitimate Internet pharmacies nationwide. Would having the power to obtain nationwide injunctions encourage more enforcement by State attorneys general against these Web sites, and would this power be consistent with traditional State authority over the practice of medicine and pharmacy?

Mr. KILGORE. It absolutely would encourage us to take action. The reluctance at this point, we can take action under State laws sometimes, but we cannot find these individuals. We need this ability so that we can join with other attorneys general and shut these down.

Mr. WAXMAN. So what we do is provide a nationwide opportunity to deal with this problem but not take away the prerogative of the States as they've traditionally dealt with some of these issues?

Mr. KILGORE. That's correct. We appreciate that.

Mr. WAXMAN. Thank you. Mr. Catizone, you testified in strong support of the two key provisions of the bill. You endorsed the establishment of Federal standards for what is a valid prescription related to Internet prescribing. You also supported giving State attorneys general the authority to shut down these sites nationwide.

I'd like to ask you about two areas where you've made some suggestions for improvement in the legislation. First, you've expressed concern about how the legislation deals with Internet service providers and search engines that might sell advertisements to illegitimate pharmacies. Are you aware of efforts by Yahoo, Google and other Internet companies to refuse to sell advertisements by some of these Internet pharmacies?

Mr. CATIZONE. Yes, I am, sir. We spoke to those search engines and they've indicated they are interested in doing so. We're not convinced that their efforts go far enough. They seem to be accepting accreditation or approval processes that don't involve a very serious inspection of those sites or very serious review of what they're doing. In fact, they probably will be accepting advertisements from Canadian pharmacies which are operating illegally.

Mr. WAXMAN. What makes this a difficult issue is that the intent of the legislation is to focus on those responsible for the illegitimate Web sites, not those who make the sites available to the public. I want to look over your suggestion, I think it's one we need to carefully consider, and I appreciate that thought behind it.

You've also made the suggestion that Internet pharmacies should participate in a formal disclosure and verification program such as the VIPPS program, which is run by the National Association of Boards of Pharmacy. You suggested that one benefit of such an approach might be better enforcement.

Are you suggesting that participating in VIPPS or in an equivalent program be required of all Internet pharmacies?

Mr. CATIZONE. Mr. Waxman, we've talked about this issue with a variety of groups and yes, we're recommending some mandatory program. The voluntary program isn't going far enough, and those sites will do anything they can to confuse consumers and to hide information. So simply requiring the posting of information that will probably be fraudulent in many cases won't help the consumers.

Mr. WAXMAN. How many participating Internet pharmacies does VIPPS certify now?

Mr. CATIZONE. We currently have 13 sites representing 8,000 to 10,000 pharmacies in the United States.

Mr. WAXMAN. And if all the Internet pharmacies were required to participate in VIPPS, how many do you think might apply?

Mr. CATIZONE. They estimate that the Internet pharmacy market is anywhere between 8 percent and 22 percent of existing pharmacies. There are probably right now 75,000 pharmacies licensed in the United States. So that number would be 8 percent to 10 percent of that, upward to 7,500 pharmacies.

Mr. WAXMAN. I appreciate the advantages of the VIPPS program. It's a model we believe the Secretary should look at when considering how to implement this bill. However, regulating a few large Internet pharmacies is not the same as monitoring what could be hundreds of thousands of Internet pharmacies. This is an enforcement challenge for anyone, whether VIPPS or FDA or the State attorneys general. We'll review this situation carefully. I think it's one that I'm pleased you brought to our attention.

Dr. Patchin, your testimony covered a wide variety of topics, but I want to ask you about a couple of specifics. You testified that current AMA policy requires physicians to prescribe via the Internet to clearly disclose physician identifying information on the Web site. Are you aware that H.R. 3880 includes this requirement as well as the requirement that pharmacies also be identified, and would you agree that the disclosure provisions in this bill are consistent with AMA policy?

Dr. PATCHIN. At this time, yes.

Mr. WAXMAN. OK, good. And you testified that AMA policy prohibits prescribing medications without a valid doctor-patient relationship. This includes performing a physical examination adequate to establish the diagnosis, having sufficient dialog with the patient regarding risks and maintaining a medial record that's readily available to the patient.

In your judgment, is a doctor who churns out prescription after prescription on the basis of little or no information through an arrangement with an Internet pharmacy in compliance with AMA policy? And are you aware that this bill prohibits Internet pharmacies from arranging for doctors to write prescriptions to consumers without ever seeing them?

Dr. PATCHIN. The physician who writes a prescription without the patient-physician relationship as we described would be in violation of AMA policy, correct.

Mr. WAXMAN. Do you think this is a good provision for accomplishing that goal?

Dr. PATCHIN. Yes.

Mr. WAXMAN. Thank you very much.

Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you very much. Mr. Carter, any questions?

Mr. CARTER. Thank you, Mr. Chairman.

When we're dealing with lawsuits in the United States, the plaintiff's bar will argue that a lot of what they do as taking actions in the plaintiff's bar is policing up organizations that don't police themselves and targeted, as AMA. But the doctors don't police up their malpractice.

Now, what I've heard testimony here today is that you would sanction, I would like to know exactly, if you were to identify a doctor who is operating this illegal procedure, what sanction would

you take with that doctor? Would you punch his ticket and stop him from practicing medicine?

Dr. THOMPSON. Yes, sir. The Federation of State medical boards is the membership association of the Nation's 70 licensing and territorial regulatory authorities. A number of licenses have been revoked and there have been disciplinary actions taken against a number of physicians that have been involved in this kind of activity. It can be anything from a slap on the hand to a license revocation. But the kind of activity that we've seen more often than not leads to revocation of a license.

Difficult, however to track these physicians down and very difficult to work across State lines in this kind of activity.

Mr. CARTER. I understand that we're giving tools to the attorneys general across the States to try to help do this. But part of the ultimate solution has to be, those people who are violating standards, violating laws and threatening lives have to be taken out of the system. If they're not taken out of the system, they're going to figure out another crooked way to do this thing.

Dr. THOMPSON. The most notorious of the individuals who deals with Internet prescriptions had a license in 26 different States, and to date has had 14 of those removed and by reciprocal action through the information services that we provide through the Federation is soon on his way to having all of his licenses revoked.

Mr. CARTER. And the same question I would direct to the people involved in pharmacy. Would the pharmacies also punch the ticket on people who are doing this what I consider illegal operation?

Dr. THOMPSON. Yes, sir.

Mr. CARTER. That's all the questions I have, Mr. Chairman. Thank you.

Chairman TOM DAVIS. Thank you very much. Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman.

Let me begin with you, Dr. Patchin. You used the term "safeguards must be in place" on two occasions. What do you mean by safeguards must be in place?

Dr. PATCHIN. Safeguards regarding the Internet prescribing would be to those that ensure that there is an approved supply of drugs that are the right dose, the right drug for the right patient, with the right, appropriate dosing interval and the right time. The safeguards for prescribing would also include State laws that govern the practice of medicine as well as the prescribing in the community standard.

Mr. TOWNS. Thank you. My concern, and I guess this is to the Attorney General, this legislation is dealing with domestic Web sites, it doesn't do anything with international Web sites. And I'm sort of concerned about the fact that once the noose is tightened that we might have a problem in terms of people going out of the country and doing almost the same thing. So what do we do here?

I'm concerned, I'm in favor of shutting down all Internet pharmacy sites. However, it appears that better oversight and controls are needed, but purchasing drugs through the Internet can offer incredible, no question about it, benefits for homebound patients. And of course, patients that might have a disease of some sort that might not want the world to know, there's benefits there as well.

But I am concerned, so I'd like to hear your comments about, once we tighten the noose, what we might run into.

Mr. KILGORE. That very well could happen. This is a great first step to control the domestic Internet companies. It's a great first step to give State attorneys general the ability to enforce the act. We recognize that as we go about enforcing the act that, as we shut down Internet pharmacies that we could see the effect you are talking about, i.e., the move overseas, they go international, then we will have to address that through our relationship with the FDA and work with the FDA and DEA on those important issues.

Mr. TOWNS. Thank you. I guess this is for the doctors on the panel. In your experience, do health care professionals typically inquire about where a patient obtains his or her prescription drug before making changes or switching to an alternative product? Is that question generally asked, where you get your medication from?

Dr. PATCHIN. Yes. Part of the assessment in obtaining the history and physical would be questions to find out what medications they are taking and who is prescribing them. You will find out where they're filling them. Many times I find out even the name of the pharmacy or the provider that they're getting their medications dispensed from.

Dr. THOMPSON. Dr. Patchin is an anesthesiologist who deals in pain management, so she's more likely dealing with the type of drugs that we're talking about. I'm an ear, nose and throat doctor, and I infrequently deal with heavy narcotics and so in my practice, I would not necessarily have known where someone filled their prescription. I would, however, know what drugs they have been taking and for what reason they have been taking them.

Mr. TOWNS. Mr. Catizone, I want to hear from you on this.

Mr. CATIZONE. That's a very critical question. We're trying to work with the physician groups to ask patients that question. Because if their blood pressure is uncontrollable or their diabetes worsens, the assumption made is that the medication is not working, so they increase the dose or change the medication, when it could be a counterfeit product or a product that has no active ingredients.

So we would also ask that be a consideration of any of these discussions. We're going to ask the FDA to change their Med Watch form to allow for that information to be asked, so they can identify whether it came from outside the U.S. distribution system.

Mr. TOWNS. Let me say, Mr. Chairman, I think this legislation is good. But the question in my mind is, does it go far enough. I would like to have an extra second or two just to run down the line and ask each member in terms of what they might want to add to make it better.

Chairman TOM DAVIS. Sure.

Dr. THOMPSON. First of all, let me say that for the purposes of addressing the problem that this committee has been confronted with, this legislation is excellent. I would applaud the Chair and the other leaders of this committee for I think superb legislation that will deal with the issue.

Chairman TOM DAVIS. Take as much time as you need. [Laughter.]

Dr. THOMPSON. There are a number of other issues, however, that relate to the technology, and we in this Nation have seen a situation in which the technology has far superseded our ability to deal with the ethics or the regulation of that technology. And quite frankly, we're playing catchup. This is a giant leap forward, I believe, for the citizens in this country. There remains much work to be done, however.

Mr. CATIZONE. I would echo Dr. Thompson's compliments on the bill. Absent the fact that we believe the disclosure should be mandatory, should be verified, in regard to the patient and the question of where the medication should be obtained from, that may not be a matter for legislation. That's a matter for the Federation and the American Medical Association to work together and increase that as a standard of care for patients as part of the diagnosis differential.

Mr. KILGORE. I totally support this legislation. It's a great move forward, and a great move to protect patients' rights in the future, and it gives certainly attorneys general around the Nation the ability to protect our consumers. The one issue I think we must deal with in the future is the important issues, so that we avoid sending mixed messages to our seniors and others in our State about whether they should be able to import drugs from foreign countries. We need to, if we allow that we need to make sure those drugs are safe, those drugs are accurate, and we continue to require a physician-patient relationship.

Dr. PATCHIN. I would like to make a plea for the patient's safety. The patient's safety is ensuring that they're getting the right drug, in the right concentration, in the right vehicle and the right timing as part of the patient-physician relationship in that prescribing.

Mr. RECTOR. We strongly endorse the legislation in each of its key provisions. We think it's carefully drawn to avoid any anti-competitive consequences by endorsing one private sector certification program over another. But a related subject, not necessarily for this committee, but perhaps, would be to carefully review the statutes that are available to prosecute those entities that are facilitating the illegal commerce, both foreign and domestic. That means the shippers and the credit card companies and others. If the subject was stolen property, there would be no question. This is a lot more serious, typically, than stolen property.

Mr. TOWNS. Thank you very much. Mr. Chairman, I don't have anything to yield back, so I'll just stop. [Laughter.]

Chairman TOM DAVIS. Thank you very much, Mr. Towns. I just want to ask a couple of followup questions.

Mr. Rector, you stated in your testimony that the regulation of the practice of pharmacy by pharmacists rests exclusively with the respective States. I just want you to reiterate again for the record the need for H.R. 3880 as a Federal law when you already have the State regulation from your perspective as a pharmacist.

Mr. RECTOR. We think that H.R. 3880 ideally complements the jurisdiction that the States enjoy, both over the practice of medicine and the practice of pharmacy.

Chairman TOM DAVIS. And the world has basically changed with the Internet, isn't that what's happened here, and everybody

agrees, that the old rules don't apply when you have such a ubiquitous communications device as the Internet?

Mr. RECTOR. Absolutely.

Chairman TOM DAVIS. And certainly, Mr. Kilgore, from an enforcement point of view it changes everything. You noted it's hard to find these people, and in many cases, you really want to join with other attorneys general to shut them down, because you're chasing them all over the globe?

Mr. KILGORE. That's true. The Internet has become the wild west, if you will, and we need this added ability in our enforcement tools to go after these rogue pharmacies.

Chairman TOM DAVIS. Let me ask you, with your experience on spammers, I know you brought one of the first cases in the country prosecuting spamming and so on, how is that going? You used one of your strongest State laws, I know, which you and Senator Stiley and Senator Devolites helped write. How has that helped and what does your experience on that tell you about this?

Mr. KILGORE. Again, it confirms our fear in the State that these cases take a lot of time, a lot of energy in our office to investigate and track down these individuals that are committing crimes. We have charts and charts that fill up a room where we've traced the ISPs from, gone to the ISP to get their address only to find out they're operating in many different domains. It just takes a lot of time and computer crunching. But we continue to investigate, just like we will once we are given this authority under this legislation to investigate and shut down these pharmacies.

Chairman TOM DAVIS. As I understand it, today, if someone is selling Lipitor and it's not Lipitor, or they're selling Viagra and it's not Viagra, you can prosecute them for that if you can run them down, is that right?

Mr. KILGORE. That is correct.

Chairman TOM DAVIS. But this gives you the additional tool, because they're doing it without a prescription, and that's probably even easier to prove, is that probably——

Mr. KILGORE. Much easier.

Chairman TOM DAVIS. Everybody understands this is just an additional tool to try and get some of these folks. In addition to that, without the appropriate medical authorization, people are at risk. The new disclosure standards ought to help identify the offending Web site, shouldn't it? We talked about pharmacies and doctors, talked about where you get it, wouldn't that help disclose the offending Web sites as well?

Mr. KILGORE. I would think it would.

Mr. CATIZONE. We think it's a first step. We think it's not going to address the issue entirely, though.

Chairman TOM DAVIS. OK. Well, thank you very much. This has been very helpful to us. We'd like to do something about that, and having the support and the testimony from your organizations is very critical in this. Again, I want to thank all the witnesses for taking their time to testify today. And the hearing is closed.

Thank you.

[Whereupon, at 12:01 p.m., the committee was adjourned, to reconvene at the call of the Chair.]

[The prepared statement of Hon. Carolyn B. Maloney and additional information submitted for the hearing record follow:]

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Statement by Congresswoman Carolyn B. Maloney
COMMITTEE ON GOVERNMENT REFORM OVERSIGHT HEARING
"A Prescription for Safety: The Need for H.R. 3880, the Internet Pharmacy Consumer Protection Act"
March 18, 2004

I'd like to thank Chairman Davis and Ranking Member Waxman for introducing HR 3880 and holding this hearing on this important bill. I'd also like to thank our witnesses for testifying today. I hope to learn how we can improve the safety of Internet sales of prescription drugs.

As the price of prescription drugs continue to rise, people across the country are looking for ways to reduce their costs. Both buyer and seller have turned to the Internet.

While I think we must work together to find ways to provide safe, effective, and affordable drugs for the consumer, I am very concerned with the number of rogue pharmacies that are plaguing the Internet and are harming consumers. It is clear that we must establish uniform regulations to safeguard pharmaceutical sales. HR 3880, which establishes a national standard for "valid prescription" is the first step toward ensuring consumers receive both medical supervision as well as the safe drugs they need.

With the ever-growing accessability of the Internet, the prevalence of prescription drug ads in the media and the lack of regulation, people are self-diagnosing, self-medicating, and self-injuring as a result. According to the National Clearinghouse for Alcohol and Drug Information, in 1999, 4 million Americans ages 12 and older had acknowledged misusing prescription drugs. This is 2% of the population which has quadrupled since 1980. Without medical supervision and increased regulation, these numbers will sadly increase.

I understand that the FDA has decided to leave it to the states to define a "valid prescription," and have only issued "cyber warning letters" which are ignored by 70% of the online pharmacies. Due to the inter-state nature of Internet commerce, states are crippled by certain regulations and licensing issues and have not dedicated much money to enforcement where they do have jurisdiction.

As I am sure we will hear, this is a serious issue and HR 3880 is a good first step toward addressing the problem. I hope we will learn how we can better protect the consumer from these fraudulent pharmacies and understand the impact of creating a valid prescription standard.

Thank you.

Ms. Harris

Submitted For The Record

March 18, 2004

Hearing: HR 3880, The Internet Pharmacy Consumer Protection Act

Opening Statement

Thank you, Mr. Chairman. I am honored to participate in today's hearing. I particularly wish to thank you for your leadership in addressing the critical issue of internet prescription drug sales. I also wish to express my appreciation to the distinguished members of today's panels for their testimony.

During recent years, pharmaceutical research has produced staggering advances, which have generated new hope for countless individuals. Similarly, through the technological marvel of the Internet, consumers now have unfettered access to significantly more choices, which they can obtain with enhanced privacy and convenience.

Internet pharmacies constitute the nexus of these amazing trends in our society. They provide easy, and often cheaper, access to the miracle drugs that are immeasurably improving

the quality of life in our nation. Nevertheless, this astounding progress possesses a dark side. Through their ability to avoid the application of state laws, internet pharmacies have opened a dangerous loophole in the regulatory system that ensures safety in the sale and use of prescription drugs.

I believe that H.R. 3880 would enact reasonable and salient solutions to many of the most obvious threats that have arisen due to the emergence of internet pharmacies. Chairman Davis and Ranking Member Waxman have demonstrated extraordinary prescience in proposing this legislation. I look forward to our consideration of H.R. 3880, as well as to our continued oversight of this critical matter.

STATEMENT BY
CONNECTICUT ATTORNEY GENERAL RICHARD BLUMENTHAL
MARCH 18, 2004

I appreciate the opportunity to speak on the issue of the domestic sale of prescription drugs over the Internet and in support H.R. 3880, the Internet Pharmacy Consumer Protection Act.

The Internet is an instrument of untapped promise and peril -- tremendous benefits and pitfalls -- especially for unwary, unaware consumers. It can enhance worker efficiency, and speed communication but also furnish fertile soil for scams and fraud.

Prescription drug Internet sales are a case in point -- fraught with risks of deception and health damage. Prescription mistakes, under-filling, or adulteration can cost money and cause serious or even fatal injury. Unlicensed pharmacies and doctors are online outlaws -- rogue medical merchants who advertise, sell, and deliver very popular and powerful prescription drugs that are readily and commonly abused. Their sales of drugs like Meridia, Xenical, Phentermine, Celebrex, and Viagra raise risks of counterfeit medicine, improper dosage, deadly interaction with prescription drugs currently used by the consumer and addiction, among other dangers. These unethical and unscrupulous practices encourage and support abuse. They make the Internet a wild west of medicine marketing.

Internet pharmacies offer one potential solution to escalating drug costs -- through real savings for consumers. Indeed, rising prescription drug costs, particularly affecting our millions of uninsured and our elderly, have created a public health crisis. Between 1997 and 2001, consumer spending on prescription drugs rose nearly 20% annually. Approximately 75% of adults between the ages of 50 and 64 years use one or more prescription drugs.

Savings available through Internet pharmacies are documented in a survey that I conducted last year on pharmacy prescription drug prices. In the survey, pharmacies across the state and six Internet pharmacies certified by the National Association of Boards of Pharmacy under their Verified Internet Pharmacy Practice site (VIPPs) were requested to provide retail prices for 30 most commonly prescribed drugs. The survey found that consumers can save hundreds of dollars each year by price comparison shopping among pharmacies.

Importantly for today's discussion, the survey also found that Internet sites had the lowest price for 18 of the 30 prescription drugs. For example, the average Internet pharmacy price for Paxil was $81.71 while the average non-Internet pharmacy price was $97.88, producing an annual savings of almost $200 for patients with typical dosages. Consumers should also be aware that the neighborhood pharmacy price for some drugs may be lower than the Internet. There may be other reasons -- such as ability to consult and confide in a resident pharmacist -- that consumers choose a local bricks and mortar establishment rather than an Internet pharmacy.

Internet pharmacies can save consumers money, but also pose a significant health and financial risks, if they are not properly licensed and regulated.

More than 400 Internet web sites offer prescription drugs. According to a 2000 Government Accounting Office report, there are typically three types of Internet pharmacies: (1) pharmacies that dispense prescription drugs only after receiving a prescription from the consumer's health care provider; (2) pharmacies that have a resident physician who provides a prescription based on consumer answers to a questionnaire; and (3) pharmacies that dispense prescription drugs without any prescription from a health care provider.

The first category of Internet pharmacies offers consumers a safe and effective alternative to a local pharmacy, often saving consumers hundreds of dollars. The second and third categories are simply disasters waiting to happen. Consumers play Russian Roulette when buying drugs without adequate professional diagnosis and review. They open their homes and health to prescription drugs that may be inappropriate, adulterated or even counterfeit.

In 2001, I filed 4 lawsuits against 7 pharmacies and 3 physicians located in other states that were illegally dispensing drugs to Connecticut consumers. These pharmacies and physicians violated Connecticut's unfair trade practices act by failing to register as a non-resident pharmacy, engaging in medical diagnosis without a license in Connecticut, advertising illegal services and requiring consumers to waive all liability claims against the pharmacy or physician.

These online outlaws sold popular and powerful drugs that are readily and commonly abused. In one instance, a pharmacy dispensed a very strong and potentially addictive diet pill to an investigator from my office who filled out a questionnaire stating that she was 5 foot 7 inches tall and weighed only 120 pounds.

State attorneys general have worked together against these rogue pharmacies. The Food and Drug Administration and the Federal Trade Commission have also brought lawsuits and taken administrative action. But the laws enforced by the states and the federal government are typically general licensure provisions and unfair trade practices acts. We need federal legislation that will provide a strong, clear, legal and direct tool for both federal and state actions.

H.R. 3880 is a great starting point for such federal regulations. The proposal requires an Internet pharmacy to provide clear and conspicuous consumer notice regarding the states in which: (1) the pharmacy is authorized to dispense prescription drugs, (2) the Internet pharmacist is licensed; and (3) the medical personnel on staff is licensed or otherwise authorized to practice medicine. This information is critical for consumers and will greatly facilitate accountability -- pinpointing responsible corporate officials if the pharmacy violates federal or state laws.

The proposal also requires any person associated with the Internet pharmacy must conduct at least one in-person medical evaluation with the consumer prior to writing any prescription for such patient.

Most significantly, the proposal provides state attorneys general with the authority to bring a civil action in a federal court for the jurisdiction in which the Internet pharmacy is located or where it transacts business. The state attorneys general may seek damages, restitution, attorneys' fees and injunctive or other equitable relief. The proposal specifically indicates that a state attorney general may seek injunctive relief that is applicable nationwide. This remedy is modeled after similar nationwide injunctive relief in the Federal Telemarketing Sales Act.

Currently, injunctive relief sought by a state attorney general is applicable only to that state, thereby necessitating 50 separate lawsuits to stop one pharmacy on a nationwide basis.

I urge the committee to support H.R. 3880 and consider additional provisions to provide an effective deterrent against illegal Internet pharmacies.

First, Congress should require that all Internet pharmacies dispense pharmaceutical drugs only with a prescription that meets standards of the state where the consumer lives. For example, Connecticut General Statutes § 20-614 requires that every prescription contain: (1) the written signature of a prescribing practitioner; (2) the address of the practitioner; (3) the date of the prescription; (4) the name, dosage form, strength and amount of the drug prescribed; (5) the name and address of the patient; (6) directions for use; (7) any required cautionary statements; and (8) the number of refills. This requirement will ensure that pertinent facts are adequately documented for every filling of the prescription.

Second, Congress should require that all Internet pharmacies comply with state licensing requirements for pharmacies. Connecticut is one of 40 states that requires every non-resident pharmacy to register before it ships, mails or delivers prescription drugs into the state. Under Connecticut General Statutes § 20-627, a non-resident pharmacy must (1) disclose annually the location, names and titles of all principal corporate officers and all pharmacists dispensing drugs to Connecticut residents; (2) provide a statement of compliance with the pharmacy licensing laws in the state in which it is located; (3) provide the most recent inspection report from the local pharmacy regulatory authority and (4) provide a toll-free telephone number for patients to contact a pharmacist who would have access to the patient's records. These basic provisions are critical to protecting public health.

Third, Congress should enact tough criminal and civil fines to deter violations.

Fourth, Congress should ensure that Internet pharmacies maintain adequate records of prescriptions filled by the pharmacy, including patient name, addresses, prescribing health care provider. Regulators should have confidential access to such information to ensure the pharmacy is complying with applicable state and federal laws.

Finally, since about half of the Internet pharmacies are based in foreign countries, Congress should prohibit the use of any financial instrument -- such as checks, money orders and electronic transfers -- to foreign Internet pharmacies that do not comply with the law. This prohibition is under consideration as an effective measure to cut the financial lifeblood of rogue, foreign based Internet gambling sites. It can be similarly effective against rogue Internet pharmacies.

The state attorneys general are willing to continue to work with the FTC, the FDA and Congress in addressing this critical public health problem.

Statement
of the

American Pharmacists Association

A Prescription for Safety: The Need for H.R. 3880

The Internet Pharmacy Consumer Protection Act

Submitted to the
Committee on Government Reform
March 18, 2004

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Statement of the American Pharmacists Association

House Committee on Government Reform

A Prescription for Safety:
The Need for H.R. 3880

The Internet Pharmacy Consumer Protection Act

The American Pharmacists Association (APhA) appreciates the opportunity to provide our perspective on the important topic of Internet access to pharmaceuticals. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 50,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians. APhA is the first-established and largest national association of pharmacists in the United States.

Internet pharmacy is a growing element of our drug distribution system. Unfortunately, unscrupulous Internet drug sellers are manipulating this process and threatening the safety of our nation's drug supply. As this practice continues to gain popularity, patient safety concerns must be considered. Prescription medications have proven to be a valuable tool in our health care system. However, that value doesn't materialize if patients receive inappropriate care — access to the "tools" without necessary health care professional support. As the medication experts on the health care team, and the health professionals dedicated to partnering with patients to improve medication use, we must share our concerns with unregulated Internet drug selling.

The ability to access medications through the Internet provides convenient access to patients. But patients need help understanding the difference between a rogue Internet drug seller and a legitimate Internet pharmacy. A legitimate Internet pharmacy is regulated by State boards of pharmacy and ideally is certified through a credible process, such as the National Boards of Pharmacy's (NABP) VIPPS[1] program. Legitimate Internet pharmacies can provide patients safe and effective medications as well as access to the most critical member of the patient's health care team when it comes to medications — their pharmacist.

Conversely, illegitimate Internet drug sellers operate outside these protections and pose safety risks to patients. A sample of the safety risks that exist with purchasing prescription medications through Internet drug sellers include:

- Internet drug sellers fail to provide access to pharmacists. Some offer medications "without a prescription", a serious breach of our regulatory system.

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[1] The VIPPS program is run by the National Association of Boards of Pharmacy (NABP). To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.

- Neither pharmacists nor patients have assurances that products sold from unregulated sellers are effective, safe, or have been produced under U.S. quality control requirements to protect against contamination.
- Because the United States regulatory authority is restricted to domestic distributors, there are no quality assurances when a drug is imported from a foreign distributor. But the Internet is world wide, thus there are no guarantees that purchases from a website purporting to be domestic are truly drugs under our regulatory system. Once a product leaves the U.S. regulatory system, the distributors are no longer held to requirements for storage conditions or product labeling.
- The actual appearance or name of some foreign medications is different from the U.S. manufactured counterpart. This may delay treatment of adverse drug reactions or side effects if a health care provider does not know what the patient is taking.
- Patients who do not tell their local pharmacist about the medications they purchased from an Internet drug seller could find themselves with a drug-to-drug interaction , a new medication that conflicts with an acute prescription. It is always best for patients to use one pharmacy to reduce the likelihood of these occurrences.
- Some Internet sites offer to prescribe medicines without a physical examination, or any interaction with the patient, bypassing the traditional prescriber-patient relationship. As a result, consumers may receive inappropriate medications because of a misdiagnosis.

The question raised by Chairman Davis is fair: are the protections outlined in H.R. 3880, the Internet Pharmacy Consumer Protection Act necessary? Absolutely. U.S. patients are increasingly offered what appear to be good deals on medications purchased through the Internet But these deals have a price — great risks to their health. These potential risks require immediate attention and we commend the Chairman for drawing attention to this public health issue. We must assist patients in distinguishing between legitimate pharmacies and illegitimate Internet drug sellers. H.R.3880 addresses several key elements necessary to curb abuses by Internet drug sellers, as identified below.

Creating Internet Pharmacy Requirements

Patient safety is the one overriding reason for the many laws and regulations that help assure Americans receive safe and effective medications—medications that are "what the doctor ordered." These controls not only guide what medications are available on the U.S. market and how those medications are manufactured, but also how they are labeled, packaged, shipped, stored, and dispensed. The current U.S. regulations were put in place after several critical incidents resulted in patient harm. When patients were harmed by contaminated or ineffective medications, Congress took action to protect patients, to provide patients with medications that do what's expected and nothing that's unexpected. By their very nature, medications are highly susceptible to counterfeiting: the products are expensive, necessary for our health, and it is difficult, if not impossible, to detect a fake product just by looking at it. Because of these challenges, Congress and state regulators established a closed system for pharmaceutical product approval and distribution. The current closed system protects American consumers from unsafe products. The Internet has created new patient safety challenges that require the same amount of due diligence by regulators.

Purchasing prescription medications through the Internet may involve patients going outside of the US and leaving our closed system, punching holes in our regulatory safety net. Those holes yield risks for patients, risks that they may receive a contaminated product, an inactive product, a product not recognizable by American pharmacists or doctors (possibly different strengths or name), a product that is not manufactured, packaged, labeled, distributed, or regulated in the country where they are purchasing the drug, or simply, the wrong product.

By opening the door—and substituting a porous system for our closed system—we risk the introduction of counterfeit medications. The World Health Organization estimates that 5 percent to 8 percent of all pharmaceuticals are counterfeit. With our current system, few consumers perceive a threat from counterfeit medications, but that changes when the safety structure is damaged. And even with the comprehensive U.S. system, counterfeit products have penetrated our system. In February, 2003, 11,000 boxes of counterfeit Epogen® and Procrit® (anemia drugs often given to cancer, AIDS and kidney failure patients) were found on pharmacy shelves and even in patients' homes. And in May, 2003, the FDA announced the discovery of three lots of counterfeit Lipitor® (cholesterol lowering medication). The FDA's continuing investigation found two additional lots of the same drug. These situations support the need for review and refinement of our existing safety net, not the expansion of efforts to circumvent or relax that system.

Therefore, we support creating requirements, new "hooks" with which we can catch illegitimate web sites and prevent their proliferation. We commend the author's inclusion of the requirement that each page of the web site, or a link to a page, provide information on "the name of each individual who serves as a pharmacist for purposes of the site, and each State in which the individual is authorized by law to dispense prescription drugs." This requirement supports our position that Internet based pharmacy web pages identify the "pharmacist in charge". Including this information helps verify that the site is legitimate while also providing a "hook" to catch illegitimate web sites: a site that provides misinformation about the pharmacist in charge or does not include the disclosure.

Requiring and Defining an "Qualifying Medical Relationship"

One of the challenges with Internet based drug sellers is that they often dispense prescription medications without the patient having a prescription prior to going to the site. To work around this patient protection, these sites are providing patients with a questionnaire, the completion of which represents a prescription to the drug seller. If there is one reason to stop illegitimate Internet drug sellers, it's the ability to sell prescription medications without the collaboration of physicians and pharmacists — bypassing the doctor/pharmacist/patient relationship. There are legitimate medical reasons why patients must get a diagnosis and prescription from their physician or other prescriber and have a pharmacist dispense the prescribed medications: medications are dangerous. Eliminating health care providers from the physician/pharmacist/patient triad of care eliminates the two "legs of the stool" who are trained to provide medical diagnoses and to provide pharmaceutical care — a combined twelve years of training.

The circumvention of U.S. health care providers creates a situation that is best described as "working in the dark." Unless the patient provides information on drugs they've purchased on

the Internet through illegitimate sellers, physicians and pharmacists have no way of knowing what a patient is taking. And because of the differences in names and physical appearances of foreign drugs, even providing the name of a product may not be enough. Pharmacists' ability to identify drug-to-drug interactions is hindered to the point of nonexistence without knowing the drug's content and strength. Consider the scenario where a patient is in need of a prescription medication on a short timeframe—such as an antibiotic for an infection or a pain medication to treat an injury. If that patient has been getting his or her medications from an illegitimate source, the pharmacist is unable to determine whether the new prescription will conflict with any other medications the patient takes, has ingredients that duplicate a current prescription, or whether its mere presence suggests other medical problems for the patient that should be followed-up with the patient's physicians. This "blindness" compromises the ability of physicians to care for their patients and the ability of pharmacists to partner with patients to improve medication use and advance patient care.

Allowing for Nationwide Enforcement
We applaud inclusion of the provision to allow States to bring a civil action on behalf of its residents and to enforce compliance, including through a nationwide injunction. One of the greatest challenges to enforcing Internet drug trade is the fact that the Internet is not limited to a state's borders — a limitation that applies to State boards of pharmacy. Even when a board of pharmacy has taken action against a rogue Internet drug website that is hosted in their state, the board has limited, if any, jurisdiction over that same website's activities in other states. This provision would allow one state to shut down activities in all 50 states of a rogue site.

Recognition of Certification Services
We appreciate the author's recognition of public and private efforts to certify Internet based pharmacies as legitimate businesses. These sites' legitimacy is the crux of this issue. However, one must be sure that these public and private entities are credible. A good example of this type of service is the National Association of Boards of Pharmacy's VIPPS program. We support the VIPPS program it allows for the continuation of state-based pharmacy regulation. A federal program could create jurisdictional confusion and would require the investment of substantial resources to create a new, arguably redundant, registration and inspection process.

National Clearinghouse Oversight & Reporting
When looking at regulating any sort of health care practice, one needs to carefully balance the needs and authorities of the federal and state regulatory bodies — the state health professions' licensing boards. H.R 3880 finds this balance. Clearly, regulation is necessary, however we cannot support steps that regulate pharmacy practice at the federal level. New regulations should not intrude upon the authority of State boards of pharmacy. Federal authorities should intervene in collaboration with a State Board of Pharmacy, similar to the Food and Drug Administration's activity with the Rx Depot case[2], and in international cases. Designating the National Clearinghouse on Internet Prescribing as the entity to identify Internet sites that appear to be in violation of State and federal laws and reporting those sites to State medical and pharmacy licensing boards strikes this important balance. An entity with federal resources and a broad perspective can keep track of national activity, and States can then use this intelligence to act against a potential rogue site within their State.

[2] 032103 warning letter by FDA to Rx Depot, Inc. http://www.fda.gov/foi/warning_letters/g3888d.pdf

Domestic vs. International
Although we generally support H.R. 3880, the proposal's impact on stemming illegal, Internet drug sellers is limited by the fact that the legislation does not address operations based outside of the United States. Most often, counterfeit medications come into the U.S. through illegitimate foreign sources. A copy of APhA's testimony to the FDA on its interim report on counterfeit medications is attached for your information. Regulating activity on the world wide web presents a great challenge. However, illegal (often offshore) Internet drug sellers pose a serious threat to health and public safety and need to be a part of the ongoing dialogue about this issue.

Stop the Source
Although not specifically addressed in the legislation, we recommend taking the lead from proposed Internet gambling regulation and address the source of payments to rogue Internet drug sellers. The US House of Representatives has seen fit to prohibit credit card payments for Internet gambling. The same type of regulation should apply to rogue Internet drug sellers. We recommend that credit card payments to illegitimate Internet-drug sellers be prohibited. Stopping the source of these payments will go a long way in stemming the activities of these rogue drug traders.

Additionally, it is very difficult to sell a product without advertising. Therefore, we recommend adding a provision that would make it illegal for Internet drug sellers to advertise on Internet search engines unless they meet a credible certification standard, such as VIPPS. This provision could also be expanded to address the issue of patient's maintaining a legitimate, "qualified" physician/patient/pharmacist relationship. To that end, we recommend making it illegal to advertise that a consumer does not need a prescription to order medications from a website.

Finally, we recommend addressing the role shippers play in the distribution of drugs purchased on the Internet. Shipment companies could play a strong role in stemming the activities of these sites by only accepting packages from pharmacies that meet the aforementioned standards. Such standard would enable members of the delivery system to identify products from legitimate pharmacies vs. illegal drug sellers.

Public Education
We also recommend addressing public education in the legislation. A public education campaign on the dangers of Internet drug sellers is an important component of regulating rogue sites. One of the best ways to accomplish this goal is by educating the very health care providers that will be working with patients daily to manage their medication therapy — pharmacists. Pharmacists already play an important role in educating patients on the dangers of illegitimate Internet drug sellers and that role will only increase as more and more patients seek to use this access point.

APhA has taken steps to educate our membership on issues surrounding importation of medications, including counterfeit medications — an issue directly related to the use of the Internet to purchase prescription medications. A continuing education piece was sent in the November issue of our monthly publication, *Pharmacy Today*, reaching more than 100,000 pharmacists. Our consumer information website, www.pharmacyandyou.org, includes

information on several topics, including information "About importing medicines and Internet pharmacies".

APhA is also working with the FDA to implement their anti-counterfeit initiative. Specifically, we will be partnering with the FDA in their communication efforts to pharmacists about counterfeit medications. An additional APhA/FDA partnership was created when we helped to develop a brochure entitled, "*Buying Prescription Medicines Online: A Consumer Safety Guide.*" The brochure was produced by the CybeRx-Smart Safety Coalition, a partnership of Internet companies, trade associations, health and consumer organizations and other government agencies. The brochure is available in hard copy from FDA, the Federal Consumer Information Center and the National Council for Patient Information and Education (member of CybeRx-Smart). It also is posted on FDA's website.

Conclusion

Medications have become a critical aspect of patient care. But prescription medications are only safe and effective when patients understand how to use them appropriately, and for what side effects they should watch. Direct interaction between the prescribers, pharmacists and patients is critical to ensuring appropriate medication use. Effective patient care is about real relationships—physician-patient, pharmacist-physician, and pharmacist-patient relationships. To remove such a basic component of our health care delivery system's safety net seems diametrically opposed to the "pro patient safety" environment we are all working to achieve.

Expansion of Internet access to medications is an attempt to provide patients with easier access to medications. Legitimate Internet pharmacy can provide a service to those homebound, or with challenges to receiving their medications from their local pharmacist, or who prefer this communication mechanism. The greatest challenge in developing policy in this area is striking the balance between roles for state and federal regulatory authorities and shutting down illegitimate drug sellers while allowing the legitimate Internet pharmacies to serve patients.

APhA thanks you for the opportunity to provide comments on this important issue. We look forward to working with the Committee to develop a safe and effective system of providing prescription medications and pharmacists services to all Americans.

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March 18, 2004

Statement for the Record by Peter Neupert
Chairman, drugstore.com

COMMITTEE ON GOVERNMENT REFORM
OVERSIGHT HEARING

"A Prescription for Safety: The Need for H.R. 3880,
the Internet Pharmacy Consumer Protection Act"

drugstore.com is a leading online drugstore and information site for health, beauty, wellness, personal care, vision and pharmacy products. The drugstore.com™ online store provides a convenient, private, and informative shopping experience that encourages consumers to buy products essential to healthy everyday living. In addition, we offer contact lenses and other vision products through our subsidiary Vision Direct. Our Web stores offer thousands of brand-name personal health care and vision products at competitive prices; a full-service, licensed retail pharmacy; and a wealth of health-related information, buying guides, and other tools designed to help consumers make informed purchasing decisions.

We share the House Government Reform Committee's concern about the safety of consumers who purchase prescription drugs over the Internet because of the increasing number of bad actors illegally selling online. We at drugstore.com spend considerable time and significant resources on this issue. We, too, believe legislative measures will need to be taken in order to protect our consumers and in order to ensure the continued integrity of our drug delivery system. The Internet Pharmacy and Consumer Protection Act represents an important starting point and we are happy to offer our thoughts on this measure and suggest how it might be made stronger to stop more illegal operators before consumers are harmed.

drugstore.com strongly believes in the power of the Internet and its ability to help individuals manage their health care needs. We believe that legitimate Internet pharmacies provide tremendous value to consumers in terms of lower retail prices, the ability to easily comparison shop, more information and detail about products, and overall greater convenience for busy, time-pressed consumers. Moreover, computer technology and the Internet provide additional opportunities to educate and inform patients about their medications and their health. For example, the Internet is a natural, inexpensive medium for delivery of compliance reminders to help ensure that patients are taking or renewing their medication. Computer technology allows

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us to automatically cross-check potential drug interactions and easily screen for health conditions that might be potential contraindications for a prescribed medication. One particularly innovative example of how technology is improving health decision making is drugstore.com's eMedAlert program, which is intended to alert our customers to critical and timely information regarding product warnings, updates, and recalls. The information in eMedAlert bulletins and notices may be provided by manufacturers, the U.S. Consumer Product Safety Commission, or the Food and Drug Administration. eMedAlert is the first notification program of its kind, designed to inform and protect our customers.

Legitimate online pharmacies such as drugstore.com are serving the growing numbers of online consumers by providing a safe, reliable, and cost-effective online drugstore. drugstore.com is licensed to dispense prescription drugs in all 50 states, we are fully HIPAA compliant and we voluntarily submit to and have been approved by a third-party verification system administered by the National Association of Boards of Pharmacy. We respect and honor the sanctity of the patient-physician relationship and adhere to American Medical Association policy by requiring patients to see a physician before doing business with our pharmacy. Before dispensing any prescription medication, we wait for the patient to mail the original prescription or communicate with the patient's doctor or existing pharmacist.

There are an alarming number of bad actors posing as legitimate online pharmacies, confusing U.S. consumers and providing them with unsafe and illegal prescription drugs, including addictive narcotic drugs. These illegal (often offshore) pharmacies are a serious threat to health and public safety. These "rogue" online pharmacies bypass the traditional doctor-patient relationship to provide medications without an actual prescription or face-to-face visit. They may provide consumers with pharmaceuticals that are expired, diluted, contaminated, or even counterfeit. One online pharmacy in Canada even collected money from unsuspecting customers but never fulfilled those orders, according to a recent report on MSNBC. And these rogue players are taking business away from and diminishing the reputation of legitimate online drugstores like drugstore.com.

We are grateful to Chairman Davis and Ranking Member Waxman for recognizing this growing threat to health and public safety and for introducing the Internet Pharmacy Consumer Protection Act. We believe, however, that stronger measures than disclosure must be taken in order to effectively stem the tide of rogue online pharmacies and ensure the integrity of our drug delivery system. We would recommend to the committee that it take a specific course of action that, we are convinced, would choke off illegal Internet pharmacies before consumers are put at risk.

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First, drugstore.com advocates creating a strict, uniform certification standard. We would recommend a program modeled after the voluntary Verified Internet Pharmacy Practice Sites, or VIPPS, standard. This standard was developed by the National Association of Boards of Pharmacy, in conjunction with a coalition of state and Federal regulatory associations, professional associations, and consumer advocacy groups, and is currently administered by the NABP. The NABP introduced this program in 1999 in response to public concern about the safety of pharmacy practices on the Internet.

To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of its state and each state to which it dispenses pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to the NABP compliance with other stringent VIPPS criteria, including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists. We would advocate that, in order to legally sell pharmaceuticals online, an organization would have to meet such a uniform certification standard. Once such a standard has been adopted and introduced, we recommend the following three-tiered approach:

1. Make it illegal for online pharmacies to advertise on search engines unless they meet the approved certification standard and prohibit search engines from accepting advertisements from online pharmacies that are not properly certified.

2. Stop credit card payment to pharmacies that do not meet the certification standard criteria (i.e., illegal pharmacies), to stop funding at the source. This would be similar to efforts by Congress to starve funding of illegal Internet gambling sites. Like Internet gambling, the activities of rogue pharmacies are illegal under U.S. law, by definition, and should be stopped. Stemming the flow of funds to these sites will largely help to accomplish that goal.

3. Motivate third party shippers to refuse shipments from pharmacies who do not meet the certification standard. One of the benefits of a clear certification standard is that the e-commerce enablers (media, payment, and delivery companies) can identify legitimate pharmacies vs. illegal operators.

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As a final point, there are multiple layers of jurisdiction regarding oversight and enforcement of our drug delivery system, and confusion exists regarding who has ultimate enforcement authority. Organizations with partial oversight and enforcement capability currently include:

- state boards of pharmacy, which are responsible for regulation and licensing of pharmacist and pharmacies, including out-of-state pharmacies;
- state medical boards, which regulate the practice of medicine, including the licensing of practitioners;
- the federal Food and Drug Administration, with jurisdiction to address misbranding of product labels appearing on packaging, misleading prescription drug advertising, importation, sale, or distribution of adulterated drugs, and misbranded drugs without a valid prescription.
- the Drug Enforcement Agency, which regulates the importation, sale or distribution of controlled substances including narcotics and other drugs deemed potentially dangerous due to potential for abuse and inherent danger;
- the Department of Justice, which enforces civil consumer protection statutes and criminal violations of the federal Food, Drug and Cosmetic Act; and
- the U.S. Customs Service and the U.S. Postal Service, which enforce statutes and regulations governing the importation and domestic mailings of drugs.

We encourage the Committee – and Congress -- to carefully examine the existing legal and regulatory structure and its adequacy to address the rogue Internet pharmacy problem. Rogue pharmacy Web sites that offer prescription drugs for sale to consumers without a valid prescription, among other illegal practices, are violating at least one law. Enforcement entities are hampered, however, by a lack of funding and other resources, including state and federal resources for cyber-tracking technology, and a lack of clear jurisdiction over foreign operators.

As rogue Internet pharmacies are investigated by the U.S. Congress, drugstore.com stands ready to act as a resource in finding the best solution to this compounding issue. U.S. consumers should feel confident that the online marketplace is as safe and secure as possible, especially with purchases that are as important to public health as prescription drugs. We are confident that the three-tiered approach outlined above will most effectively address this growing public health problem.

NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Statement

On the

Internet Pharmacy Consumer Protection Act (HR 3880)

Before the

Committee on Government Reform
U.S. House of Representatives
Washington, D.C.

March 18, 2004

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Mr. Chairman and members of the Committee. The National Association of Chain Drug Stores (NACDS) is pleased to submit a statement for the record of this important hearing on the **"Internet Pharmacy Consumer Protection Act" (H.R. 3880).**

NACDS represents more than 210 chain pharmacy companies operating about 35,000 community retail pharmacies. Our members are the primary providers of outpatient prescription services in the United States, filling more than 70 percent of the 3.4 billion prescriptions dispensed in 2003. A growing number of our members provide services through the Internet.

Internet Access to Pharmacy Provides Convenience for Patients: In this age of immediate information and consumer convenience, most retail businesses have Internet sites available to consumers. In particular, retail pharmacies maintain Internet sites that provide consumers with convenient access to their products and services. The vast majority of legitimate pharmacy-based Internet sites are operated by traditional state-licensed "brick-and-mortar" pharmacies that maintain those sites for the convenience of their patients. These sites allow patients to order prescription refills and non-prescription items. Most of the legitimate sites do not allow ordering of new prescriptions, other than perhaps to allow a patient to ask a pharmacist to call the patient's physician, where a legitimate medical relationship has already been established. Legitimate retail pharmacy Internet sites are not affiliated with, and do not provide, a prescriber for the patient.

While there are a handful of legitimate, state-licensed pharmacies whose only connection to consumers is via an Internet site, we are well aware of the existence of rogue Internet sites, both domestic and foreign, that are engaged in a pattern of illegal activity regarding the prescribing and dispensing of prescription medications. We deplore these activities. Policymakers have legitimate concerns about the patient safety implications of prescription medications sold through these rogue Internet-based entities. These entities sell prescription medications, usually without a legitimate medical relationship with the consumer, and even without a valid prescription. Many of these so-called "pharmacies" are not licensed by any state or other jurisdiction, and are shipping unapproved, counterfeit, mislabeled, or adulterated products within or into the United States.

NACDS wants to work with Members of Congress and regulators to eliminate these rogue illegal Internet suppliers from the market. Foreign-based pharmacies that attempt to falsely represent themselves as U.S.-based Internet sites are a major source of the dangerous, unapproved, and adulterated pharmaceuticals being shipped into the United States.

Elimination of these sites and their sources of supply could significantly reduce the flow of illegal products into this country. Federal Internet pharmacy legislation must target the elimination of these sites, without adversely impacting legitimate traditional "brick-and-mortar" pharmacies that merely operate an Internet site.

The impact of any new Federal regulation of the Internet could also have unintended consequences. For example, we know that the recently-enacted Medicare legislation requires the Secretary to create standards for the electronic transmission of prescriptions from physicians to pharmacies. Sending prescriptions electronically offers great promise both in terms of enhancing patient safety and assuring cost-effective drug therapy. However, we are concerned that attempts to regulate the transmission of legitimate prescriptions – both new and refill – over the Internet from physicians to pharmacies could stifle the many benefits that are available through electronic prescribing. The point is that legitimate pharmacies should not inadvertently be included in legislation targeting illegal entities.

Legitimate Pharmacies are Already Highly Regulated by the States: State boards have effectively regulated the practices of medicine and pharmacy for more than 100 years. We are concerned that Federal regulation of Internet pharmacies will ultimately lead to Federal regulation of pharmacy practice. That is, we are concerned that Federal regulation of Internet pharmacies, as contemplated by H.R. 3880, would result in de facto Federal regulation of all pharmacies – including traditional brick-and-mortar pharmacies that have Internet sites. That will occur unless Federal legislation distinguishes between traditional brick-and-mortar pharmacies with Internet connections that are already licensed by state boards of pharmacy, versus pharmacies whose primary method of access by consumers is via the Internet, where there is no state board licensure.

Currently, all pharmacies must be licensed by the state in which the pharmacy resides, including those that have Internet access. Many states also require licenses for out-of-state pharmacies that ship or mail pharmaceuticals into the state to residents; in other words, many states require non-resident pharmacy licenses. To secure and maintain their state licenses, all legitimate pharmacies must comply with voluminous regulations, which are continuously updated. Illegal "pharmacies" are those without state licenses. State pharmacy boards do not have the authority to license foreign pharmacies, irrespective of their legitimacy status abroad. Any Federal legislation should not subject state-licensed pharmacies to further regulation, simply because they provide consumers the option of ordering via an Internet site.

Issues Relating to H.R. 3880

Our perspectives on H.R. 3880, as well as other Federal initiatives to regulate Internet pharmacies, will be based on several criteria that assess their impact on our customers and our industry.

Entities Subject to Legislation: The entities that an Internet pharmacy bill will seek to regulate must be carefully defined, since the broader the definition, the more likely that traditional brick-and-mortar pharmacies with Internet sites will be swept into the regulations.

For example, proposals such as H.R. 3880 that broadly regulate pharmacies if any part of the prescription ordering or sales transaction is conducted through an Internet site are problematic. Legitimate state-licensed pharmacies that merely operate Internet sites for the purposes of allowing patients to order refill prescriptions could be subject to this bill. This would be duplicative of the existing state-based retail pharmacy regulatory scheme.

NACDS is also concerned that the language in the bill could prohibit legitimate pharmacies from contacting physicians for prescription refills through the Internet. Because the language indicates that a pharmacy may not dispense a prescription if the patient did not have a prescription for the drug when the communication began, a prescription with no more refills, for example, would no longer be a valid prescription. This raises several questions about whether a pharmacist can use the Internet, or an electronic prescribing technology that is Internet-based, to contact a prescriber to obtain permission to obtain permission to create a new prescription for that drug.

We believe that legislation must be narrowly tailored to affect only the offending entities that are not licensed as a pharmacy in the United States, or are operating overseas. For these reasons, we believe that an Internet pharmacy should be defined as a pharmacy that: (1) uses the Internet as the primary method to facilitate the ordering of a prescription and the receipt of prescriptions for filling; (2) uses mail or commercial carriers as the primary method to deliver the prescriptions to patients; and (3) is not licensed by the board of pharmacy in the states in which they operate, and to which they are sending prescription drugs.

Internet Disclosure Requirements: H.R. 3880 and other proposals would require Internet pharmacies to disclose certain information, similar to the information that traditional pharmacies have already posted in their stores about licenses, pharmacists, and certain other information as required by state boards of pharmacy. The goal of any Internet pharmacy legislation would be to provide consumers with sufficient information to assess the legitimacy of the Internet pharmacy and assure that consumers can make an informed decision about whether they want to obtain a prescription drug from an Internet site. NACDS believes that such information can be helpful to consumers in assessing the quality of the Internet site.

However, H.R. 3880 could be interpreted to require every community pharmacy that has an Internet site to post on the site information relating to the names and licensure status of its pharmacists for each pharmacy that it operates. Duplicative and burdensome "posting" requirements should not be imposed on legitimate retail pharmacies simply because they operate an Internet site.

For example, a pharmacy chain of 400 stores that has an Internet ordering connection might be required to post on its website licensure information about each and every one of its pharmacists at each and every one of its stores. Many pharmacists are licensed in multiple states, which requires the pharmacy operator to know significant licensure information about the pharmacist beyond that which is already require to practice in

their own state. Finally, pharmacists often change pharmacy practice locations, making it impossible to accurately maintain this type of information on an Internet site. The burden of this requirement is obviously greater for chains with thousands of operating units. This would create significant burdens for pharmacies to continually update their Internet sites.

These burdens are duplicative, because pharmacy stores are already required by state boards of pharmacy to visibly post this information in each pharmacy outlet. Therefore, brick-and-mortar pharmacies with Internet sites should not have to aggregate and post this information on their sites if the information is already posted in their individual stores.

Certification of Internet Pharmacies: Many legitimate pharmacies have already invested substantial resources in obtaining certification of their Internet site under the National Association of Boards of Pharmacy (NABP) Verified Internet Pharmacy Practice Sites (VIPPS) certification program. NABP is the professional association that represents the state boards of pharmacy in all U.S. jurisdictions. In response to public concerns regarding the safety of pharmacy practices on the Internet, NABP developed the VIPPS program in 1999. A coalition of state and federal regulatory associations, professional associations, and consumer advocacy groups provided their expertise in developing the criteria that VIPPS-certified pharmacies follow. To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists. The VIPPS program can be considered the gold standard for Internet pharmacy certification programs. The VIPPS program requires rigorous certification and recertification of pharmacies that have Internet sites. Fourteen pharmacies have VIPPS certification, and many other are currently engaged in the VIPPS certification process.

This VIPPS "seal of approval" should be sufficient for consumers and policymakers to be sure that the Internet site is legitimate and will provide quality pharmacy services to consumers. This recognition of VIPPS certification is not included in H.R. 3880. It would be redundant for pharmacies with Internet sites that are certified by VIPPS to also have to meet Federal requirements. Additionally, we are concerned that multiple Internet pharmacy certification programs may cause public confusion, and may require conflicting and substandard certification requirements.

State Causes of Action and Penalties: H.R. 3880 would give state attorneys general the authority to enforce certain provisions of Federal Food, Drug, and Cosmetic Act by seeking nationwide injunctions against Internet pharmacies. A nationwide injunction would prohibit the Internet pharmacy from doing business in all states, rather than just the state in which the state attorney general is located.

We recognize that the state attorneys general may want this authority to help shut down illegal entities on a nationwide basis, so that each state attorney general does not have to bring separate actions in their own states. However, we are concerned that this proposal represents an overly broad grant of authority that would give state attorneys general nationwide jurisdiction to take action against legitimate brick-and-mortar pharmacies that happen to have Internet sites.

With billions of prescriptions being filled each year, pharmacies could inadvertently and unknowingly violate the Food, Drug and Cosmetics Act . Thus, it is possible that this new authority could result in aggressive action by a state attorney general against a nationwide or regional chain for unintended violations of the Food, Drug and Cosmetics Act, simply because they provide consumers with an Internet connection.

Rather than grant nationwide federal powers to states attorneys general, Congress should grant the U.S. Department of Justice discretion to intervene in actions filed by state attorneys general to enforce the Federal Food, Drug and Cosmetics Act. The Department of Justice could then seek a nationwide injunction against an illegal Internet pharmacy. That would respect the principles of federalism while shutting down illegal Internet pharmacies.

Beyond leveling fines against Internet pharmacies that violate the law, penalties should also be assessed against prescribers that order prescriptions for consumers outside a valid physician-patient relationship. Success in eliminating the dispensing of prescriptions from illegal entities will only be reached if all contributing entities are targeted for violations.

Another concern is that H.R. 3880 shields from liability the advertisers of illegal Internet pharmacies. Advertisers should not be exempt from liability when they publicize illegal drug sales over the Internet. The bill should be revised to state that advertisers may be held liable when they know or reasonably should have known that they are aiding and abetting illegal drug sales.

Workable Solutions: Despite our reservations, NACDS has seen favorable provisions in proposals we believe would help eliminate illegal Internet entities that sell prescription drugs. NACDS encourages the following:

- Narrowly limit the definition of Internet pharmacy to exclude legitimate, state-licensed brick-and-mortar pharmacies in this new regulatory structure, and specifically target rogue Internet pharmacies.
- Encourage and empower federal and state agencies to work together to enforce existing laws against illegal Internet pharmacies in federal and state courts.
- Clearly identify legitimate pharmacy Internet sites through a credible and thorough certification program.
- Educate consumers about the dangers of dealing with illegal Internet pharmacies, and provide a convenient method for consumers to report suspected

illegal entities to state boards of medicine and pharmacy, and to the state attorneys general, for investigation.
- Require a pharmacy that maintains an interactive consumer Internet site to list on the site the states in which it maintains valid pharmacy licenses.

Conclusion

NACDS agrees that illegal Internet "pharmacies" present patient health and safety concerns. However, existing laws and regulations have not been adequately enforced that could rectify many of the problems that already exist.

We have concerns that many proposals create an unprecedented beachhead for FDA to regulate the practices of medicine and pharmacy, which traditionally have been the authority of the states. While illegal Internet entities must be shut down by Congress and the states, consumer access to prescription medications through legitimate pharmacies must be protected. We look forward to working with this Committee and the Congress in defining that appropriate balance and achieving the overarching goal of eliminating rogue Internet operations that threaten our drug supply and patient safety.